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**UNITED STATES BANKRUPTCY COURT
DISTRICT OF NEW JERSEY**

In re:

INVITAE CORPORATION, *et al.*,

Debtors.¹

Chapter 11

Case No. 24-11362 (MBK)

(Jointly Administered)

¹ The last four digits of Debtor Invitae Corporation's tax identification number are 1898. A complete list of the Debtors in these chapter 11 cases and each such Debtor's tax identification number may be obtained on the website of the Debtors' claims and noticing agent at www.kcellc.net/invitae. The Debtors' service address in these chapter 11 cases is 1400 16th Street, San Francisco, California 94103.



**DECLARATION OF JEFFREY GOLDFINE IN SUPPORT OF THE DEBTORS’
OBJECTION TO THE OFFICIAL COMMITTEE OF UNSECURED CREDITORS’
MOTION FOR (I) LEAVE, STANDING AND AUTHORITY TO COMMENCE AND
PROSECUTE CERTAIN CLAIMS AND CAUSES OF ACTION ON BEHALF OF
DEBTORS’ ESTATES AND (II) EXCLUSIVE SETTLEMENT AUTHORITY**

I, Jeffrey Goldfine, declare pursuant to 28 U.S.C. § 1746 as follows:

1. I am a partner at Kirkland & Ellis LLP and co-counsel to the Debtors in the above captioned cases. I offer this declaration in support of the *Debtors’ Objection to the Official Committee of Unsecured Creditors’ Motion for (I) Leave, Standing and Authority to Commence and Prosecute Certain Claims and Causes of Action on Behalf of Debtors’ Estates and (II) Exclusive Settlement Authority* (the “Objection”).¹ This declaration is based on my personal knowledge and upon my review of the records of this and related matters.

2. Attached as Exhibit 1 is a true and correct copy of Invitae’s Form 10-K for 2018.

3. Attached as Exhibit 2 is a true and correct copy of Invitae’s Form 10-K for 2021.

4. Attached as Exhibit 3 is a true and correct copy of Invitae’s Form 10-K for 2020.

5. Attached as Exhibit 4 is a true and correct copy of Invitae’s Form 10-K for 2022.

6. Attached as Exhibit 5 is a true and correct copy of Invitae’s Form 10-Q for the first quarter of 2023.

7. Attached as Exhibit 6 is a true and correct copy of a Form 8-K filed by Invitae on or about June 18, 2020.

8. Attached as Exhibit 7 is a true and correct copy of a Form 8-K filed by Invitae on or about June 26, 2020.

¹ Capitalized terms used but not immediately defined are defined shall have the meaning ascribed to them in the Objection filed contemporaneously herewith.

9. Attached as Exhibit 8 is a true and correct copy of a Form 8-K filed by Invitae on or about May 4, 2021.

10. Attached as Exhibit 9 is a true and correct copy of a Form 8-K filed by Invitae on or about April 14, 2022.

11. Attached as Exhibit 10 is a true and correct copy of a Form 8-K filed by Invitae on or about July 16, 2022.

12. Attached as Exhibit 11 is a true and correct copy of a Form 8-K filed by Invitae on or about August 25, 2022.

13. Attached as Exhibit 12 is a true and correct copy of a press release issued by Invitae on or about February 28, 2023.

14. Attached as Exhibit 13 is a true and correct copy of a Form 8-K filed by Invitae on or about April 6, 2023.

15. Attached as Exhibit 14 is a true and correct copy of a Form 8-K filed by Invitae on or about October 19, 2023.

16. Attached as Exhibit 15 is a true and correct copy of a Form 8-K filed by Invitae on or about December 14, 2023.

17. Attached as Exhibit 16 is a true and correct copy of a Form 8-K filed by Invitae on or about January 18, 2024.

18. Attached as Exhibit 17 is a true and correct copy of a Form 8-K filed by Invitae on or about January 22, 2024.

19. Attached as Exhibit 18 is a true and correct copy of minutes of a meeting of Invitae's Board of Directors, dated June 3, 2022.

20. Attached as Exhibit 19 is a true and correct copy of minutes of a meeting of Invitae's Board of Directors, dated October 13, 2022.

21. Attached as Exhibit 20 is a true and correct copy of a document presented to Invitae's Board of Directors, entitled "Discussion Materials for Project Icon," dated October 13, 2022.

22. Attached as Exhibit 21 is a true and correct copy of minutes of a meeting of the Finance Committee of Invitae's Board of Directors, dated January 20, 2023.

23. Attached as Exhibit 22 is a true and correct copy of an excerpt from a presentation to Invitae's Board of Directors, dated January 26, 2023.

24. Attached as Exhibit 23 is a true and correct copy of the Monthly Business Review presented to Invitae's Board of Directors, dated February 15, 2023.

25. Attached as Exhibit 24 is a true and correct copy of minutes of a meeting of the Finance Committee of Invitae's Board of Directors, dated February 1, 2023.

26. Attached as Exhibit 25 is a true and correct copy of minutes of a meeting of the Compensation Committee of Invitae's Board of Directors, dated February 2, 2023.

27. Attached as Exhibit 26 is a true and correct copy of minutes of a meeting of the Finance Committee of Invitae's Board of Directors, dated February 10, 2023.

28. Attached as Exhibit 27 is a true and correct copy of minutes of a meeting of the Compensation Committee of Invitae's Board of Directors, dated February 22, 2023.

29. Attached as Exhibit 28 is a true and correct copy of minutes of a meeting of the Finance Committee of Invitae's Board of Directors, dated February 24, 2023.

30. Attached as Exhibit 29 is a true and correct copy of minutes of a meeting of Invitae's Board of Directors, dated February 25, 2023.

31. Attached as Exhibit 30 is a true and correct copy of a presentation to Invitae's Board of Directors, dated February 25, 2023.

32. Attached as Exhibit 31 is a true and correct copy of a presentation to the Pricing Committee of Invitae's Board of Directors, dated February 28, 2023.

33. Attached as Exhibit 32 is a true and correct copy of minutes of a meeting of the Compensation Committee of Invitae's Board of Directors, dated March 9, 2023.

34. Attached as Exhibit 33 is a true and correct copy of a document presented to Invitae's Board of Directors, entitled "Discussion Materials," dated July 2023.

35. Attached as Exhibit 34 is a true and correct copy of minutes of a meeting of the Compensation Committee of Invitae's Board of Directors, dated September 15, 2023.

36. Attached as Exhibit 35 is a true and correct copy of minutes of a meeting of the Compensation Committee of Invitae's Board of Directors, dated September 21, 2023.

37. Attached as Exhibit 36 is a true and correct copy of minutes of the Special Committee of Invitae's Board of Directors, dated October 18, 2023.

38. Attached as Exhibit 37 is a true and correct copy of a unanimous written consent of Invitae's Board of Directors, dated October 18, 2023.

39. Attached as Exhibit 38 is a true and correct copy of a document presented to Invitae's Board of Directors, entitled "Deerfield Consent Proposal and Comparison," dated November 14, 2023.

40. Attached as Exhibit 39 is a true and correct copy of minutes of a meeting of the Compensation Committee of Invitae's Board of Directors, dated January 5, 2024.

41. Attached as Exhibit 40 is a true and correct copy of minutes of a meeting of Invitae's Board of Directors, dated January 7, 2024.

42. Attached as Exhibit 41 is a true and correct copy of minutes of a meeting of the Compensation Committee of Invitae’s Board of Directors, dated January 9, 2024.

43. Attached as Exhibit 42 is a true and correct copy of minutes of a meeting of Invitae’s Board of Directors, dated January 11, 2024.

44. Attached as Exhibit 43 is a true and correct copy of a Solvency Certificate, dated March 7, 2023.

45. Attached as Exhibit 44 is a true and correct copy of a letter from Invitae Corporation to Deerfield Management Co., L.P., dated January 26, 2024.

46. Attached as Exhibit 45 is a true and correct copy of a report entitled “Project Ionic, Financial Overview for UCC and Advisors,” dated April 2, 2024.

47. Attached as Exhibit 46 is a true and correct copy of transcripts of auction proceedings in the above-captioned case, dated April 17, 2024 and April 24, 2024.

48. Attached as Exhibit 47 is a true and correct copy of a Form 8-K filed by Invitae on or about March 1, 2023.

49. Attached as Exhibit 48 is a true and correct copy of the Amended and Restated Certificate of Incorporation of Invitae Corporation, dated February 18, 2015.

50. Attached as Exhibit 49 is a true and correct copy of an article from Wells Fargo Equity Research, entitled “Plenty is Never Enough: Tools, EDx Tough; CROs Safer?”, dated October 15, 2021.

51. Attached as Exhibit 50 is a true and correct copy of a report from J.P. Morgan, entitled “Growth Life Science Tools & Diagnostics,” dated January 6, 2022.

52. Attached as Exhibit 51 is a true and correct copy of a Cowen Equity Research report regarding “Invitae Corp.,” dated July 26, 2022.

53. Attached as Exhibit 52 is a true and correct copy of an article from Reorg Research, entitled “Wesco Aircraft Liability Management - Witness Testimony Concludes on Day 30 of Incora/Wesco Trial,” dated June 7, 2024.

54. Attached as Exhibit 53 is a true and correct copy of a memorandum of law in support of the motion to dismiss filed by the defendants in *U.S. Bank Trust Co., NA v. DISH DBS Corp., et al.*, No. 1:24-cv-3646 (JGLC) (S.D.N.Y.), on or about June 27, 2024.

55. Attached as Exhibit 54 is a true and correct copy of the transcript of the deposition of David Dunn, dated June 26, 2024.

[Remainder of page intentionally left blank]

I declare under penalty of perjury that the foregoing is true and correct.

Dated: July 2, 2024

/s/ Jeffrey Goldfine

Jeffrey Goldfine (admitted *pro hac vice*)

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*Co-Counsel to the Debtors and
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EXHIBIT 1

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____
Commission File No. 001-36847



Invitae Corporation

(Exact name of the registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

27-1701898
(I.R.S. Employer
Identification No.)

1400 16th Street, San Francisco, California 94103
(Address of principal executive offices, Zip Code)

(415) 374-7782
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:

Common Stock, par value \$0.0001 per share

Name of each exchange on which registered:

The New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of June 29, 2018, the aggregate market value of common stock held by non-affiliates of the Registrant was approximately \$477.8 million, based on the closing price of the common stock as reported on The New York Stock Exchange for that date.

The number of shares of the registrant’s Common Stock outstanding as of February 22, 2019 was 76,811,562.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III incorporate by reference information from the registrant’s proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant’s 2019 Annual Meeting of Stockholders.

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PART I

ITEM 1. Business.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this report other than statements of historical fact, including statements identified by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect” and similar expressions, are forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our views regarding the future of genetic testing and its role in mainstream medical practice;
- our mission and strategy for our business, products and technology, including our ability to expand our content and develop new content while maintaining attractive pricing, further enhance our genetic testing service and the related user experience, build interest in and demand for our tests and attract potential partners;
- the implementation of our business model;
- the expected benefits, including cost-savings and synergies, from our acquisitions;
- the rate and degree of market acceptance of our tests and genetic testing generally;
- our ability to scale our infrastructure and operations in a cost-effective manner;
- the timing of and our ability to introduce improvements to our genetic testing platform and to expand our assay to include additional genes;
- our expectations with respect to future hiring;
- the timing and results of studies with respect to our tests;
- developments and projections relating to our competitors and our industry;
- our competitive strengths;
- the degree to which individuals will share genetic information generally, as well as share any related potential economic opportunities with us;
- our commercial plans, including our sales and marketing expectations;
- our ability to obtain and maintain adequate reimbursement for our tests;
- regulatory developments in the United States and foreign countries;
- our ability to attract and retain key scientific or management personnel;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our ability to obtain funding for our operations and the growth of our business, including potential acquisitions;
- our financial performance;
- the impact of accounting pronouncements and our critical accounting policies, judgments, estimates and assumptions on our financial results;
- our expectations regarding our future revenue, cost of revenue, operating expenses and capital expenditures, and our future capital requirements; and
- the impact of tax laws on our business.

Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Item 1A of this report. Although we believe that the expectations and assumptions reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statements in this report speak only as of the date of this report. We expressly disclaim any obligation or undertaking to update any forward-looking statements.

This report contains statistical data and estimates that we obtained from industry publications and reports. These publications typically indicate that they have obtained their information from sources they believe to be reliable, but do not guarantee the accuracy and completeness of their information. Some data contained in this report is also based on our internal estimates. Although we have not independently verified the third-party data, we believe it to be reasonable.

In this report, all references to “Invitae,” “we,” “us,” “our,” or “the company” mean Invitae Corporation.

Invitae and the Invitae logo are trademarks of Invitae Corporation. We also refer to trademarks of other companies and organizations in this report.

Overview

Combining genetic testing services that support patient care throughout life’s journey – from inherited disease diagnosis, to family planning, to proactive health screening – with a unique, rapidly expanding network of patients, healthcare providers, biopharma and advocacy partners, Invitae is capturing the broad potential of genetics and helping to expand its use across the healthcare continuum. Through the custom design and application of automation, robotics and bioinformatics software solutions tailored to the complexity of sample processing and complex variant interpretation, Invitae can apply its world-class clinical expertise to medical interpretation at scale, simplifying the process of obtaining and utilizing affordable, high-quality genetic information to inform critical healthcare decisions.

By pioneering new ways of sharing and understanding genetic information, Invitae is transforming the field of genetics from one-dimensional testing to complex information management.

Mission and strategy

Invitae’s mission is to bring comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people. Our goal is to aggregate a majority of the world’s genetic information into a comprehensive network that enables sharing of data among network participants to improve healthcare and clinical outcomes.

We were founded on four core principles:

- Patients should own and control their own genetic information;
- Healthcare professionals are fundamental in ordering and interpreting genetic information;
- Driving down the price of genetic information will increase its clinical and personal utility; and
- Genetic information is more valuable when shared.

Our strategy for long-term growth centers on five key drivers of our business, which we believe work in conjunction to create a flywheel effect extending our leadership position in the new market we are building:



- **Expanding our content offering.** We intend to continue steadily adding additional content to the Invitae platform, ultimately leading to affordable access to the personal molecular information relevant

in enabling personalized medicine. The breadth and depth of our offering is a core and central contribution to an improved user experience.

- **Creating a unique user experience.** A state-of-the-art interactive platform will enhance our service offering, leverage the uniquely empowering characteristics of online sharing of genetic information and, we believe, enable a superior economic offering to clients. We intend to continue to expend substantial efforts developing, acquiring and implementing technology-driven enhancements to our customers' experience. We believe that an enhanced user experience and the resulting benefits to our brand and reputation will help draw customers to us over and above our direct efforts to do so.
- **Driving volume.** We intend to increase our brand equity and visibility through excellent service and a variety of marketing and promotional techniques, including scientific publications and presentations, sales, marketing, public relations, social media and web technology vehicles. We believe that rapidly increasing the volume of customers using our platform helps us to attract partners.
- **Attracting partners.** As we add more customers to our platform, we believe our business becomes particularly attractive to potential partners that can help the patients in our network further benefit from their genetic information or that provide us access to new customers who may wish to join our network. We believe the cumulative effect of the increased volume brought by all of these strategic components will allow us to lower the cost of our service.
- **Lowering the cost and price of genetic information.** Our goal is to provide customers with a broad menu of genetic content at a reasonable price and rapid turn-around time in order to grow volume and further achieve economies of scale. As we do so and benefit from further cost savings, we expect that those cost savings will allow us to deliver still more comprehensive information at decreasing prices and further improve the customer experience, allowing us to reap the cumulative benefits from all of the efforts outlined above.

We seek to differentiate our service in the market by establishing an exceptional experience for our customers. To that end, we believe that elevating the needs of the customer over those of our other stakeholders is essential to our success. Thus, in our decision-making processes, we will strive to prioritize, in order:

- The needs of our customers;
- Motivating our employees to serve our customers; and
- Our long-term stockholder value.

We are certain that focusing on customers as our top priority rather than short-term financial goals is the best way to build and operate an organization for maximum long-term value creation.

Business overview

We are focused on making comprehensive, high-quality genetic information more accessible by lowering the cost of genetic testing, by creating a network of partners to increase the utility of genetic information across the healthcare continuum, and ultimately by managing that information on behalf of our customers.

As our market share grows, we expect that our business will grow in three stages:

- 1) **Genetic testing:** making genetic testing more affordable and more accessible with fast turnaround time. We believe that there is a significant market opportunity for high-volume, low-cost genetic testing that allows us to serve a large number of customers. We launched our first commercial offering in November 2013 with an offering of approximately 200 genes, growing the test menu over time to include more than 20,000 genes to help diagnose disease, inform family planning, and serve healthy individuals. In 2018, we accessioned approximately 303,000 samples and generated revenue of \$147.7 million reflecting an approximate 102% and 117% increase over 2017 volume and revenue, respectively. In 2018, we achieved a full-year gross profit of \$67.6 million, compared to a full-year gross profit of \$18.1 million in 2017. In support of our efforts to reduce the cost per test, expand our test menu, and develop a scalable laboratory infrastructure, we incurred research and development expenses of \$63.5 million, \$46.5 million and \$44.6 million in 2018, 2017, and 2016, respectively.
- 2) **Genome network:** sharing genetic information on a global scale to advance science and medicine. We are focusing our efforts on partnering with patients, family members, healthcare professionals, payers, industry professionals, researchers, and clinical trial sponsors to advance the development of our

genome network. Our goal is to build a network through which individuals can access, aggregate, and customize information based on their genotype and phenotype and participate in new research, clinical trials, treatment planning, or other related purposes that may benefit the individual and/or their clinician. Individuals can also decide to share information if they feel it will benefit them or will contribute more broadly to furthering knowledge about their conditions.

In addition to investing in informatics solutions and infrastructure to support network development, we have begun partnering with biopharmaceutical companies, including Alnylam Pharmaceuticals, Inc., Ariad Pharmaceuticals, Inc. (a subsidiary of Takeda Pharmaceutical Company Limited), AstraZeneca, BioMarin Pharmaceutical Inc., Blueprint Medicines Corporation, Jazz Pharmaceuticals plc, Merck & Co., Inc., MyoKardia, Inc., Parion Sciences, Inc. and others to support clinical trial recruitment and other research-related initiatives. Our biopharmaceutical industry partnerships are complemented by partnerships with leading health systems, executive health programs and leading research institutions, including the Geisinger Health System, the Mayo Clinic, Memorial Sloan Kettering Cancer Center, MedCan, NorthShore University HealthSystem, and Stanford Health Care, among others.

- 3) **Genome management:** building a secure and trusted genome management infrastructure. By generating and storing large amounts of individualized genetic information for every patient sample, we believe we can create value over the course of disease or lifetime of a customer.

Competition

Our competitors include companies that offer molecular genetic testing services, including specialty and reference laboratories that offer traditional single and multi-gene tests. Principal competitors include companies such as Ambry Genetics, a subsidiary of Konica Minolta Inc.; Athena Diagnostics, a subsidiary of Quest Diagnostics Incorporated; Baylor Genetics; Blueprint Genetics, Inc.; Centogene AG; Color Genomics, Inc.; Connective Tissue Gene Test LLC; Cooper Surgical, Inc.; Eurofins Scientific; GeneDx, a subsidiary of OPKO Health, Inc.; Laboratory Corporation of America Holdings; MNG Laboratories, LLC; Myriad Genetics, Inc.; Natera, Inc.; Perkin Elmer, Inc.; PreventionGenetics, LLC; Progenity, Inc.; Quest Diagnostics Incorporated; and Sema4 Genomics; as well as other commercial and academic labs. In addition, there are a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness, including Illumina, Inc. which is also one of our suppliers. In addition to the companies that currently offer traditional genetic testing services and research centers, other established and emerging healthcare, information technology and service companies may commercialize competitive products including informatics, analysis, integrated genetic tools and services for health and wellness.

We believe the principal competitive factors in our market are:

- breadth and depth of content;
- quality;
- reliability;
- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;
- convenience of testing;
- brand recognition of test provider;
- additional value-added services and informatics tools;
- client service; and
- quality of website content.

We believe that we compare favorably with our competitors on the basis of these factors. However, many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, substantially greater financial, technological and research and development resources and selling and marketing capabilities, and more experience dealing with third party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests, or sell their tests at prices designed to win significant levels of market share. We may not be able to compete effectively against these organizations.

Regulation

Reimbursement

In September 2014, the American Medical Association, or AMA, published new Current Procedural Terminology, or CPT, codes for genomic sequencing procedures that are effective for dates of service on or after January 1, 2015. These include genomic sequencing procedure codes for panels, including hereditary colon cancer syndromes, targeted genomic sequence analysis panels for solid organ neoplasms, targeted genomic sequence analysis panels for hematolymphoid neoplasm or disorders, whole exome analyses, and whole genome analyses. In a final determination under the Medicare Clinical Laboratory Fee Schedule, or CLFS, published in November 2014, the Centers for Medicare and Medicaid Services, or CMS, set the 2015 payment rate for these codes by the gap-fill process. Under the gap-fill process, local Medicare Administrative Contractors, or MACs, establish rates for those codes that each MAC believes meet the criteria for Medicare coverage and considering laboratory charges and discounts to charges, resources, amounts paid by other payers for the tests, and amounts paid by the MAC for similar tests. In 2015, gap-filled payment rates were established for some, but not all, of the above-referenced codes. For those codes for which local gap-filled rates were established in 2015, a national limitation amount for Medicare was established for 2016. Codes for which local gap-filled rates were not established in 2015 were priced by the local MACs in 2016 insofar as an individual MAC determined that such codes should be covered. Where available, the national limitation amount serves as a cap on the Medicare and Medicaid payment rates for a test procedure. If we are required to report our tests under these codes, there can be no guarantees that Medicare (or its contractors) has or will set adequate reimbursement rates for these codes.

The AMA also released several CPT codes effective January 2016 that may be appropriate to report certain of our tests. In a November 2015 final determination, CMS set the calendar year 2016 CLFS payment rate for these new codes by the gap-fill process. CMS and the local MACs went through the gap-fill process in 2016 and announced final gap-filled rates for 2017 on September 30, 2016. The calendar year 2017 national limitation amounts for certain codes were significantly less than the rates at which we have historically offered our tests.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under the regulations implementing PAMA, laboratories that realize at least \$12,500 in Medicare CLFS revenues during the six month reporting period and that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule must report, beginning in 2017, and then every three years thereafter (or annually for "advanced diagnostic laboratory tests"), private payer payment rates and volumes for their tests. We do not believe that our tests meet the current definition of advanced diagnostic laboratory tests, and therefore believe we are required to report private payer rates for our tests on an every three years basis. CMS uses the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil money penalties.

As set forth under the regulations implementing PAMA, for tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are paid based upon these reported private payer rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the cross-walk or gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test.

The payment rates calculated under PAMA went into effect starting January 1, 2018. Where applicable, reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020 and to 15% per test per year in each of 2021 through 2023 (following a second round of private payer rate reporting in 2020 to establish rates for 2021 through 2023).

PAMA codified Medicare coverage rules for laboratory tests by requiring any local coverage determination to be made following the local coverage determination process. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory-specific MACs. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate. It is unclear whether CMS will proceed with contractor consolidation under this authorization.

PAMA also authorized the adoption of new, temporary billing codes and/or unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The American Medical Association has created a new section of billing codes, Proprietary Laboratory Analyses, to facilitate implementation of this section of PAMA. At this time, it is unclear how these codes would apply to our tests.

In March 2018, CMS published a final national coverage determination, or NCD, for next generation sequencing, or NGS, tests for patients with advanced cancer. The final NCD establishes full coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays when offered for their FDA-approved or FDA-cleared use(s), ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer) who have not previously been tested with the same test for the same primary diagnosis of cancer or are seeking repeat testing for a new primary cancer diagnosis, and have decided to seek further cancer treatment. The final NCD also gives MACs the authority to establish local coverage for NGS-based assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It is unclear, however, whether MACs retain the authority to establish local coverage for NGS-based tests provided for patients with cancer that do not meet the above-referenced criteria - e.g., patients with earlier stage cancers or patients with a personal history of cancer - or if such tests are nationally non-covered under the NCD. If CMS interprets the final NCD to exclude coverage for patients with earlier stage cancers or patients with a personal history of cancer, MACs will no longer have discretion to cover our current tests when offered to such patients, notwithstanding historical Medicare coverage for such tests. An interpretation of the NCD that results in Medicare non-coverage for our current and future assays would have significant negative impact on our business, financial condition, and results of operations.

Clinical Laboratory Improvement Amendments of 1988, or CLIA

Our clinical reference laboratories in California are required to hold certain federal certificates to conduct our business. Under CLIA, we are required to hold certificates applicable to the type of laboratory examinations we perform and to comply with standards covering personnel, facilities administration, inspections, quality control, quality assurance and proficiency testing. In 2018, we closed our laboratory in Cambridge, Massachusetts and transferred operations from that facility to our laboratory in San Francisco, California.

We have current certifications under CLIA to perform testing at our laboratory locations in San Francisco and Irvine, California. To renew our CLIA certifications, we are subject to survey and inspection every two years to assess compliance with program standards. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

If our clinical reference laboratories are out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificates, as well as directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties. We must maintain CLIA compliance and certifications to be eligible to bill for diagnostic services provided to Medicare and Medicaid beneficiaries. If we were to be found out of compliance with CLIA requirements and subjected to sanction, our business could be harmed.

State laboratory licensure

We are required to maintain in-state licenses to conduct testing in California. California laws establish standards for day-to-day operations of our laboratories in San Francisco and Irvine. Such laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratories. If our clinical reference laboratories are out of compliance with California standards, the California Department of Health Services, or DHS, may suspend, restrict or revoke our licenses to operate our clinical reference laboratories, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business. We maintain current licenses in good standing with DHS. However, we cannot provide assurance that DHS will at all times in the future find us to be in compliance with all such laws.

Several states require the licensure of out-of-state laboratories that accept specimens from those states and/or receive specimens from laboratories in those states. Our laboratories hold the required out-of-state laboratory licenses for Maryland, New York, Pennsylvania, and Rhode Island.

In addition to having laboratory licenses in New York, our clinical reference laboratories in California are also required to obtain approval on a test-specific basis by the New York State Department of Health, or NYDOH, before specific testing is performed on samples from New York.

Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of human blood or saliva necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States.

U.S. Food and Drug Administration, or FDA

We provide our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by CLIA and state law, respectively).

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. Subsequently, on January 13, 2017, the FDA published a "discussion paper" in which the agency outlined a substantially revised "possible approach" to the oversight of LDTs. The discussion paper explicitly states that it is not a final version of the 2014 draft guidance and that it does not represent the agency's "formal position;" rather, the discussion paper describes the evolution of the agency's thinking on LDTs, which the agency posted to "spur further dialogue." Notably, in the discussion paper, the agency expressed its willingness to consider "grandfathering" currently marketed LDTs from most or all FDA regulatory requirements. It is unclear at this time when, or if, the FDA will finalize its plans to end enforcement discretion, and even then, the new regulatory requirements are expected to be phased-in over time. Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time-to-time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time.

If the FDA ultimately regulates certain LDTs as medical devices, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements for medical devices can be expensive, time-consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's medical device requirements to our tests could materially and adversely affect our business, financial condition, and results of operations.

Notwithstanding the FDA's current position with respect to oversight of our tests, we may voluntarily decide to pursue FDA pre-market review for our current tests and/or tests we may offer in the future if we determine that doing so would be appropriate from a strategic perspective – e.g., if CMS indicated that it no longer intended to cover tests offered as LDTs.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

In addition, in November 2013, the FDA issued final guidance regarding the distribution of products labeled for research use only. Certain of the reagents and other products we use in our tests are labeled as research use only products. Certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

HIPAA and HITECH

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, the U.S. Department of Health and Human Services issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and requirements for protecting the privacy and security of protected health information used or disclosed by covered entities, including health care providers and their respective business associates, including the business associates' subcontractors. Four principal regulations with which we are required to comply have been issued in final form under HIPAA and HITECH: privacy regulations, security regulations, the breach notification rule, and standards for electronic transactions, which establish standards for common healthcare transactions.

The privacy regulations cover the use and disclosure of protected health information by covered entities as well as business associates, which are persons or entities that perform certain functions for or on behalf of a covered entity that involve the creation, receipt, maintenance, or transmittal of protected health information. Business associates are defined to include a subcontractor to whom a business associate delegates a function, activity, or service, other than in the capacity of the business associate's workforce. As a general rule, a covered entity or business associate may not use or disclose protected health information except as permitted under the privacy regulations. The privacy regulations also set forth certain rights that an individual has with respect to his or her protected health information maintained by a covered entity or business associate, including the right to access or amend certain records containing his or her protected health information, or to request restrictions on the use or disclosure of his or her protected health information.

Covered entities and business associates also must comply with the security regulations, which establish requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. In addition, HITECH established, among other things, certain breach notification requirements with which covered entities and business associates must comply. In particular, a covered entity must notify any individual whose unsecured protected health information is breached according to the specifications set forth in the breach notification rule. A covered entity must also notify the Secretary of the U.S. Department of Health and Human Services and, under certain circumstances, the media of a breach of unsecured protected health information.

The HIPAA privacy, security, and breach notification regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information or insofar as such state laws apply to personal information that is broader in scope than protected health information as defined under HIPAA. Massachusetts, for example, has a state law that protects the privacy and security of personal information of Massachusetts residents. Many states also have laws or regulations that specifically apply to the use or disclosure of genetic information and that are more stringent than the standards under HIPAA.

There are significant civil and criminal penalties that may be imposed on a covered entity or business associate for violating HIPAA. A covered entity or business associate may also be liable for civil money penalties for a violation that is based on an act or omission of any of its agents, including a downstream business associate, as determined according to the federal common law of agency. Additionally, to the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

Federal and state consumer protection laws

The Federal Trade Commission, or FTC, is an independent U.S. law enforcement agency charged with protecting consumers and enhancing competition across broad sectors of the economy. The FTC's primary legal authority comes from Section 5 of the FTC Act, which prohibits unfair or deceptive acts or practices in the marketplace. The FTC has increasingly used this broad authority to police data privacy and security, using its powers to investigate and bring lawsuits. Where appropriate, the FTC can seek a variety of remedies, such as but not limited to the implementation of comprehensive privacy and security programs, biennial assessments by independent experts, monetary redress to consumers, and provision of robust notice and choice mechanisms to consumers. In addition to its enforcement mechanisms, the FTC uses a variety of tools to protect consumers' privacy and personal information, including pursuing enforcement actions to stop violations of law, conducting studies and issuing reports, hosting public workshops, developing educational materials, and testifying before the U.S. Congress on issues that affect consumer privacy.

The vast majority of cases brought by the FTC fall under the “deceptive” prong of Section 5. These cases often involve a failure on the part of a company to adhere to its own privacy and data protection principles set forth in its policies. To avoid Section 5 violations, the FTC encourages companies to build privacy protections and safeguards into relevant portions of the business, and consider privacy and data protection as the company grows and evolves. In addition, privacy notices should clearly and accurately disclose the type(s) of information the company collects, how the company uses and shares the information, and the security measures used by the company to protect the information.

In recent years, the FTC’s enforcement under Section 5 has included alleged violations of the “unfairness” prong. Many of these cases have alleged that companies were unfair to consumers because they failed to take reasonable and necessary measures to protect consumer data. The FTC has not provided bright line rules defining what constitutes “reasonable and necessary measures” for implementing a cybersecurity program, but it has provided guidance, tips and advice for companies. The FTC has also published past complaints and consent orders, which it urges companies use as examples to help avoid an FTC enforcement action, even if a data breach or loss occurs.

In addition to the FTC Act, most U.S. states have unfair and deceptive acts and practices statutes, or UDAP statutes, that substantially mirror the FTC Act and have been applied in the privacy and data security context. These vary in substance and strength from state to state. Many have broad prohibitions against unfair and deceptive acts and practices, while New York’s UDAP statute, for instance, is limited to only deceptive acts and practice. These statutes generally allow for private rights of action and are enforced by the states’ Attorneys General. In addition, every U.S. state has a data breach notification law that requires entities to report certain security incidents to affected consumers and state regulators.

International privacy and data protection laws

There are a growing number of jurisdictions all over the world that have privacy and data protection laws. These laws are typically triggered by a company’s establishment or physical location in the jurisdiction, data processing activities that take place in the jurisdiction, and/or the processing of personal information about individuals located in that jurisdiction. Certain international privacy and data protection laws, such as those in the European Union, can be more restrictive and prescriptive than those in the U.S., while other jurisdictions can have laws less restrictive or prescriptive than those in the U.S. Enforcement of these laws vary from jurisdiction to jurisdiction, with a variety of civil or criminal penalties.

The European Union’s General Data Protection Regulation, or GDPR, took effect in May 2018. The GDPR applies to any business, regardless of its location, that provides goods or services to residents in the European Union. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for “sensitive information” which includes health and genetic information of data subjects residing in the European Union. The GDPR also grants individuals various rights in relation to their personal data including the right to access, rectification, objection to processing and deletion, and provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR and the related national data protection laws of the member states of the European Union, which may deviate slightly from the GDPR, may result in significant fines.

Federal, state and foreign fraud and abuse laws

In the United States, there are various fraud and abuse laws with which we must comply, and we are potentially subject to regulation by various federal, state and local authorities, including CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, and individual U.S. Attorney offices within the Department of Justice, and state and local governments. We also may be subject to foreign fraud and abuse laws.

In the United States, the federal Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering of any good, facility, service or item for which payment may be made in whole or in part by a federal healthcare program. Many courts have held that the Anti-Kickback Statute may be violated if any one purpose of the remuneration is to induce or reward patient referrals or other federal healthcare program business, regardless of whether there are other legitimate purposes for the arrangement. The definition of “remuneration” has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, consulting fees, waivers of co-payments,

ownership interests, and providing anything at less than its fair market value. The Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry. The Anti-Kickback Statute includes several statutory exceptions, and the U.S. Department of Health and Human Services has issued a series of regulatory “safe harbors.” These exceptions and safe harbor regulations set forth certain requirements for various types of arrangements, which, if met, will protect the arrangement from potential liability under the Anti-Kickback Statute. Although full compliance with the statutory exceptions or regulatory safe harbors ensures against liability under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific statutory exception or regulatory safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. Penalties for violations of the Anti-Kickback Statute are severe, and include imprisonment, criminal fines, civil money penalties, and exclusion from participation in federal healthcare programs. Many states also have anti-kickback statutes, some of which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

There are also federal laws related to healthcare fraud and false statements, among others, that apply to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payer programs such as the Medicare and Medicaid programs. The false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payer programs.

Another development affecting the healthcare industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act’s “whistleblower” or “qui tam” provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payer program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by presenting or causing to be presented a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each false claim. For penalties assessed after January 29, 2018, whose associated violations occurred after November 2, 2015, the penalties range from \$11,181 to \$22,363 for each false claim. The minimum and maximum per claim penalty amounts are subject to annual increases for inflation.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and some of these state laws apply where a claim is submitted to any third-party payer and not only a governmental payer program.

Additionally, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or for a claim that is false or fraudulent. This law also prohibits the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier for items or services reimbursable by Medicare or a state healthcare program. There are several exceptions to the prohibition on beneficiary inducement.

A recently enacted law, the Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”), prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA’s reach extends beyond federal health care programs, to include private insurance (i.e., it is an “all payer” statute). For purposes of EKRA, the term “laboratory” is defined broadly and without reference to any connection to substance use disorder treatment. EKRA is a criminal statute and violations can result in fines of up to \$200,000, up to 10 years in prison, or both, per violation. The law includes a limited number of exceptions, some of which closely align with corresponding Anti-Kickback Statute exceptions and safe harbors and others that materially differ.

In Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery

Act 2010. Under the new regime, an individual found in violation of the Bribery Act 2010, faces imprisonment of up to ten years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

Physician referral prohibitions

A federal law directed at “self-referrals,” commonly known as the “Stark Law,” prohibits a physician from referring a patient to an entity for certain Medicare-covered designated health services, including laboratory services, if the physician, or an immediate family member, has a financial relationship with the entity, unless an exception applies. The Stark Law also prohibits an entity from billing for services furnished pursuant to a prohibited referral. A physician or entity that engages in a scheme to circumvent the Stark Law’s referral prohibition may be fined up to \$100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per service, an assessment of up to three times the amount claimed and possible exclusion from participation in federal healthcare programs. Bills submitted in violation of the Stark Law may not be paid by Medicare, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states have comparable laws that apply to services covered by other third-party payers. The Stark Law also prohibits state receipt of federal Medicaid matching funds for services furnished pursuant to a prohibited referral. This provision of the Stark Law has not been implemented by regulations, but some courts have held that the submission of claims to Medicaid that would be prohibited as self-referrals under the Stark Law for Medicare could implicate the False Claims Act.

Corporate practice of medicine

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging clinicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. For example, California’s Medical Board has indicated that determining what diagnostic tests are appropriate for a particular condition and taking responsibility for the ultimate overall care of the patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings.

Intellectual property

We rely on a combination of intellectual property rights, including trade secrets, copyrights, trademarks, customary contractual protections and, to a lesser extent, patents, to protect our core technology and intellectual property. With respect to patents, we believe that the practice of patenting individual genes, along with patenting tools and methods specific to individual genes, has impeded the progress of the genetic testing industry beyond single gene tests and is antithetical to our core principle that patients should own and control their own genomic information. In recent years the U.S. Supreme Court has issued a series of unanimous (9-0) decisions setting forth limits on the patentability of natural phenomena, natural laws, abstract ideas and their applications—*i.e.*, *Mayo Collaborative v. Prometheus Laboratories* (2012), or *Mayo*, *Association for Molecular Pathology v. Myriad Genetics* (2013), or *Myriad*, and *Alice Corporation v. CLS Bank* (2014), or *Alice*. As discussed below, we believe the *Mayo*, *Myriad* and *Alice* decisions bring clarity to the limits to which patents may cover specific genes, mutations of such genes, or gene-specific technology for determining a patient’s genomic information.

Patents

U.S. Supreme Court cases have clarified that naturally occurring DNA sequences are natural phenomena, which should not be patentable. On June 13, 2013, the U.S. Supreme Court decided *Myriad*, a case challenging the validity of patent claims held by Myriad relating to the cancer genes BRCA1 and BRCA2. The *Myriad* Court held that genomic DNAs that have been isolated from, or have the same sequence as, naturally occurring samples, such as the DNA constituting the BRCA1 and BRCA2 genes or fragments thereof, are not eligible for patent protection. Instead, the *Myriad* Court held that only those complementary DNAs (cDNAs) which have a sequence that differs from a naturally occurring fragment of genomic DNA may be patent eligible. Because it will be applied by other courts to all gene patents, the holding in *Myriad* also invalidates patent claims to other genes and gene variants. Prior to *Myriad*, on August 16, 2012, the U.S. Court of Appeals for the Federal Circuit had held that certain patent claims of Myriad directed to methods of comparing or analyzing BRCA1 and BRCA2 sequences to determine whether or not a person has a variant or mutation are unpatentable abstract processes, and Myriad did not appeal such ruling.

We do not currently have any patents or patent applications directed to the sequences of specific genes or variants of such genes, nor do we rely on any such in-licensed patent rights of any third party. We believe that correlations between specific gene variants and a person's susceptibility to certain conditions or diseases are natural laws that are not patentable under the U.S. Supreme Court's decision in *Mayo*. The *Mayo* case involved patent claims directed to optimizing, on a patient-specific basis, the dosage of a certain drug by measuring its metabolites in a patient. The *Mayo* Court determined that patent claims directed at detection of natural correlations, such as the correlation between drug metabolite levels in a patient and that drug's optimal dosage for such patient, are not eligible for patent protection. The *Mayo* Court held that claims based on this type of comparison between an observed fact and an understanding of that fact's implications represent attempts to patent a natural law and, moreover, when the processes for making the comparison are not themselves sufficiently inventive, claims to such processes are similarly patent-ineligible. On June 19, 2014, the U.S. Supreme Court decided *Alice*, where it amplified its *Mayo* and *Myriad* decisions and clarified the analytical framework for distinguishing between patents that claim laws of nature, natural phenomena and abstract ideas and those that claim patent-eligible applications of such concepts. According to the *Alice* Court, the analysis depends on whether a patent claim directed to a law of nature, a natural phenomenon or an abstract idea contains additional elements, an "inventive concept," that "is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself;" (citing *Mayo*).

We believe that *Mayo*, *Myriad* and *Alice* not only render as unpatentable genes, gene fragments and the detection of a person's sequence for a gene, but also have the same effect on generic applications of conventional technology to specific gene sequences. For example, we believe that generic claims to primers or probes directed to specific gene sequences and uses of such primers and probes in determining a person's genetic information are not patentable. We do not currently have any patents or patent applications directed to such subject matter nor have we in-licensed such patents rights of any third party.

Unlike patents directed to specific genes, we do rely upon, in part, patent protection to protect technology that is not gene-specific and that provides us with a potential competitive advantage as we focus on making comprehensive genetic information less expensive and more broadly available to our customers. In this regard, we have issued U.S. patents, pending U.S. patent applications and corresponding non-U.S. patents and patent applications directed to various aspects of our laboratory, analytic and business practices. We intend to pursue further patent protection where appropriate.

Trade secrets

In addition to seeking patent protection for some of our laboratory, analytic and business practices, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain and develop our competitive position. We have developed proprietary procedures for both the laboratory processing of patient samples and the analysis of the resulting data to generate clinical reports. For example, we have automated aspects of our processes for curating information about known variants, identifying variants in an individual's sequence information, associating those variants with known information about their potential effects on disease, and presenting that information for review by personnel responsible for its interpretation and for the delivery of test reports to clinicians. We try to protect these trade secrets, in part, by taking reasonable steps to keep them confidential. This includes entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees and certain third parties. We also enter into invention or patent assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we may not enter into such agreements with all relevant parties, and these parties may not abide by the terms of their agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy or independently develop and commercially exploit aspects of our technology or obtain and use information that we regard as proprietary.

Trademarks

We work hard to achieve a high level of quality in our operations and to provide our customers with a superior experience when interacting with us. As a consequence, our brand is very important to us, as it is a symbol of our reputation and representative of the goodwill we seek to generate with our customers. As a consequence, we have invested significant resources in protection of our trademarks.

Environmental matters

Our operations require the use of hazardous materials (including biological materials) that subject us to a variety of federal, state and local environmental and safety laws and regulations. Some of these regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or new regulations will affect our business, operations or the cost of compliance.

Raw materials and suppliers

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Illumina, Inc., Integrated DNA Technologies Incorporated, Qiagen N.V., Roche Holdings Ltd. and Twist Bioscience Corporation for certain laboratory reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot assure you that we would be able to secure alternative equipment, reagents and other materials, or bring such equipment, reagents and materials on line and revalidate them without experiencing interruptions in our workflow. If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business and reputation could be adversely affected.

Customer concentration

We receive payment for our tests from partners, patients, institutional customers and third-party payers. As of December 31, 2018, substantially all our revenue has been derived from test reports generated from our assays. A single payer accounted for 22%, 13%, and 11% of our revenue for the years ended December 31, 2018, 2017, and 2016, respectively.

Employees

We had 788 employees as of December 31, 2018.

General Information

We were incorporated in the State of Delaware on January 13, 2010 under the name Locus Development, Inc. and changed our name to Invitae Corporation in 2012. In February 2015 we completed an initial public offering of our common stock.

Our principal executive offices are located at 1400 16th Street, San Francisco, California 94103, and our telephone number is (415) 374-7782. Our website address is www.invitae.com. The information contained on, or that can be accessed through, our website is not part of this annual report on Form 10-K.

We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC. You may obtain a free copy of these reports in the Investor Relations section of our website, www.invitae.com. All reports that we file are also available at www.sec.gov.

ITEM 1A. Risk Factors.

Risks related to our business and strategy

We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.

We have incurred substantial losses since our inception. For the years ended December 31, 2018, 2017 and 2016, our net losses were \$129.4 million, \$123.4 million and \$100.3 million, respectively. At December 31, 2018, our accumulated deficit was \$516.7 million. While our revenue has increased over time, we expect to continue to incur significant losses. In addition, these losses may increase as we focus on scaling our business and operations and expanding our testing capabilities, which may increase our operating expenses. In addition, as a result of the integration of acquired businesses, we may be subject to unforeseen or additional expenditures, costs or liabilities. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity, working capital and stock price. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We began operations in January 2010 and commercially launched our initial assay in late November 2013; accordingly, we have a relatively limited operating history upon which you can evaluate our business and prospects. Our limited commercial history makes it difficult to evaluate our current business and makes predictions about our future results, prospects or viability subject to significant uncertainty. Our prospects must be considered in light of the risks and difficulties frequently encountered by companies in their early stage of development, particularly companies in new and rapidly evolving markets such as ours. These risks include an evolving and unpredictable business model and the management of growth. To address these risks, we must, among other things, increase our customer base; implement and successfully execute our business and marketing strategy; identify, acquire and successfully integrate companies, assets or technologies in areas that are complementary to our business strategy; successfully enter into other strategic collaborations or relationships; obtain access to capital on acceptable terms and effectively utilize that capital; identify, hire and successfully integrate additional employees; continue to expand, automate and upgrade our laboratory, technology and data systems; obtain, maintain and expand coverage and reimbursement by healthcare payers; provide rapid test turnaround times with accurate results at low prices; provide superior customer service; respond to competitive developments; and attract, retain and motivate qualified personnel. We cannot assure you that we will be successful in addressing these risks, and the failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations.

We have acquired and may continue to acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.

As part of our business strategy, we have pursued and may continue to pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. As an organization, we have limited experience with respect to acquisitions as well as the formation of strategic alliances and joint ventures.

In 2017, we established a leading position in family health genetic information services through the strategic acquisition of reproductive health testing capabilities, which included our acquisition of Good Start Genetics, Inc., or Good Start, a molecular diagnostics company focused on preimplantation and carrier screening for inherited disorders, and CombiMatrix Corporation, a company specializing in prenatal diagnosis, miscarriage analysis and pediatric developmental disorders. In 2017 we also acquired AltaVoice, formerly PatientCrossroads, a patient-centered data company with a global platform for collecting, curating, coordinating and delivering safeguarded data from patients and clinicians, and Ommdom, Inc. and its product, CancerGene Connect, an end-to-end platform for collecting and managing genetic family histories to deliver personalized genetic risk information.

With respect to our acquired businesses and any acquisitions we may make in the future, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Furthermore, the loss of customers, payers, partners or suppliers following the completion of any acquisitions by us could harm our business. For example, we experienced a reduction in Good Start's sales as a result of the termination of a contract by a third-party laboratory that had performed expanded carrier screening for Good Start. Changes in services, sources of revenue, and branding or rebranding initiatives may involve substantial costs and may not be favorably received by customers, resulting in an adverse impact on our financial results, financial condition and stock price. Integration of an acquired company or business also may require management's time and resources that otherwise would be available for ongoing development of our existing business. For example, we diverted resources from other projects in order to develop an expanded carrier screening test as a result of the termination of the third-party laboratory contract with Good Start. We may also need to divert cash from other uses in order to fund these integration activities. Ultimately, we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment, or these benefits may take longer to realize than we expected.

To finance any acquisitions or investments, we may raise additional funds. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. In addition, our stockholders may experience substantial dilution as a result of additional securities we may issue for acquisitions. Open market sales of substantial amounts of our common stock issued to stockholders of companies we acquire could also depress our share price. Alternatively, we may raise additional funds for our acquisition activities through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all. In addition, our 2018 Note Purchase Agreement limits our ability to merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock and make investments, in each case subject to certain exceptions.

If third-party payers, including managed care organizations, private health insurers and government health plans do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.

Our ability to increase the number of billable tests and our revenue will depend on our success achieving reimbursement for our tests from third-party payers. Reimbursement by a payer may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary, cost-effective and has received prior authorization.

Since each payer makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payer to cover and the amount it will reimburse for our tests will likely be made on an indication by indication basis. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our test from most of the large commercial third-party payers in the United States, and the Centers for Medicare and Medicaid Services, or CMS, provides reimbursement for our multi-gene tests for hereditary breast cancer-related disorders as well as colon cancer. We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from third-party payers may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. In cases where there is not

a contracted rate for reimbursement, there is typically a greater coinsurance or copayment requirement from the patient, which may result in further delay or decreased likelihood of collection.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payer to payer, and we have needed additional time and resources to comply with them. We have also experienced, and may continue to experience, delays in or denials of coverage if we do not adequately comply with these requirements. Our third-party payers have also requested, and in the future may request, audits of the amounts paid to us. We could be adversely affected if we are required to repay these or other payers for alleged overpayments due to lack of compliance with their reimbursement policies. In addition, we have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests and any future tests we may develop. If we fail to expand and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure, commercial operations, research and development activities and pursue acquisitions. We believe our existing cash and cash equivalents as of December 31, 2018, revenue from sales of our tests and available debt under our 2018 Note Purchase Agreement will be sufficient to meet our anticipated cash requirements for our currently-planned operations for the 12-month period following the filing date of this report. We may need additional funding to finance operations prior to achieving profitability, or should we make additional acquisitions. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings, if available, could impose significant restrictions on our operations. Our obligations under our 2018 Note Purchase Agreement are subject to covenants, including quarterly covenants to achieve certain revenue levels as well as additional covenants, including limits on our ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions. Our obligations under our 2018 Note Purchase Agreement are secured by a security interest on substantially all of our and certain of our subsidiaries' assets.

The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, selling and marketing initiatives, or potential acquisitions. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to our company.

We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the market. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.

With the development of next generation sequencing, the clinical genetics market is becoming increasingly competitive, and we expect this competition to intensify in the future. We face competition from a variety of sources, including:

- dozens of relatively specialized competitors focused on inherited clinical genetics and gene sequencing, such as Ambry Genetics, Inc., a subsidiary of Konica Minolta Inc., Athena Diagnostics, a subsidiary of

Quest Diagnostics Incorporated, Baylor Genetics, Blueprint Genetics, Inc., Centogene AG, Color Genomics, Inc., Connective Tissue Gene Test LLC, Cooper Surgical, Inc., Eurofins Scientific, GeneDx, a subsidiary of OPKO Health, Inc., MNG Laboratories, LLC, Myriad Genetics, Inc., Natera, Inc., Perkin Elmer, Inc., PreventionGenetics, LLC, Progenity, Inc. and Sema4 Genomics;

- a few large, established general testing companies with large market share and significant channel power, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated;
- a large number of clinical laboratories in an academic or healthcare provider setting that perform clinical genetic testing on behalf of their affiliated institutions and often sell and market more broadly; and
- a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness including Illumina, Inc., which is also one of our suppliers.

Hospitals, academic medical centers and eventually physician practice groups and individual clinicians may also seek to perform at their own facilities the type of genetic testing we would otherwise perform for them. In this regard, continued development of equipment, reagents, and other materials as well as databases and interpretation services may enable broader direct participation in genetic testing and analysis.

Participants in closely related markets such as clinical trial or companion diagnostic testing could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide such potential competitors with significant advantages.

In addition, the biotechnology and genetic testing fields are intensely competitive both in terms of service and price, and continue to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

We believe the principal competitive factors in our market are:

- breadth and depth of content;
- quality;
- reliability;
- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;
- convenience of testing;
- brand recognition of test provider;
- additional value-added services and informatics tools;
- client service; and
- quality of website content.

Many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, higher margins on their tests, substantially greater financial, technological and research and development resources, selling and marketing capabilities, lobbying efforts, and more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do, sell their tests at prices designed to win significant levels of market share, or obtain reimbursement from more third-party payers and at higher prices than we do. We may not be able to compete effectively against these organizations. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payers are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies as use of next generation sequencing for clinical diagnosis and preventative care increases. Certain of our competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to website and systems development than we

can. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. In addition, some of our competitors have obtained approval or clearance for certain of their tests from the U.S. Food and Drug Administration, or FDA. If payers decide to reimburse only for tests that are FDA-approved or FDA-cleared, or if they are more likely to reimburse for such tests, we may not be able to compete effectively unless we obtain similar approval or clearance for our tests. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.

Our expected future growth could create a strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as it grows. We will likely need to continue expanding our sales force to facilitate our growth, and we may have difficulties locating, recruiting, training and retaining sales personnel. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. As we grow, any failure of our controls or interruption of our production facilities or systems will have a larger impact on our business and financial operations. We plan to implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain, and failure to complete these activities in a timely and efficient manner could adversely affect our operations. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed. Future growth in our business could also make it difficult for us to maintain our corporate culture.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including protected health information, personally identifiable information, credit card information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. We also communicate sensitive patient data through our Invitae Family History Tool, Patient Insights Network, or PIN, and CancerGene Connect platform. In addition to storing and transmitting sensitive personal information that is subject to myriad legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions in our business and operations. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take what we believe to be reasonable and appropriate measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information, such as but not limited to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH, state data security and data breach notification laws, and related regulatory penalties. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, our Invitae Family History Tool, PIN and CancerGene Connect platform are currently accessible through our online portal and/or through our mobile

applications, and there is no guarantee we can protect our online portal or our mobile applications from breach. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business.

In addition to security risks, we also face privacy risks. While we have policies that govern our privacy practices and procedures that aim to keep our practices consistent with such policies, such procedures are not invulnerable to human error. Should we inadvertently break the privacy promises we make to patients or consumers, we could receive a complaint from an affected individual or interested privacy regulator, such as the FTC or a state Attorney General. This risk is heightened given the sensitivity of the data we collect.

Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include civil monetary penalties of up to \$1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to \$50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Penalties for unfair or deceptive acts or practices under the FTC Act or state Unfair and Deceptive Acts and Practices, or UDAP, statutes may also vary significantly.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. The European Union's General Data Protection Regulation, or GDPR, took effect in May 2018. The GDPR applies to any business, regardless of its location, that provides goods or services to residents in the European Union. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the European Union. The GDPR also grants individuals various rights in relation to their personal data including the right to access, rectification, objection to processing and deletion, and provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR and the related national data protection laws of the member states of the European Union, which may deviate slightly from the GDPR, may result in significant fines.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 28, 2018, California adopted the California Consumer Privacy Act of 2018, or CCPA and amended the law in September 2018 to exempt all protected health information (PHI) collected by certain parties subject to HIPAA. The effective date of the CCPA is January 1, 2020; however, legislators have stated that they intend to propose amendments to the CCPA before it goes into effect. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation.

It is possible the GDPR, CCPA and other data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country and state to state, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We can provide no assurance that we are or will remain in compliance with diverse privacy and security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and security requirements could result in civil or criminal penalties, which could have a material adverse effect on our business.

We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.

Our performance, including our research and development programs and laboratory operations, largely depend on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization, including software developers, geneticists, biostatisticians, certified laboratory scientists and other

scientific and technical personnel to process and interpret our genetic tests. In addition, we expect the need to continue to expand our sales force with qualified and experienced personnel. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to scale our business, support our research and development efforts and our clinical laboratory. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

We need to scale our infrastructure in advance of demand for our tests, and our failure to generate sufficient demand for our tests would have a negative impact on our business and our ability to attain profitability.

Our success depends in large part on our ability to extend our market position, to provide customers with high quality test reports quickly and at a lower price than our competitors, and to achieve sufficient test volume to realize economies of scale. In order to execute our business model, we intend to continue to invest heavily in order to significantly scale our infrastructure, including our testing capacity and information systems, expand our commercial operations, customer service, billing and systems processes and enhance our internal quality assurance program. We expect that much of this growth will be in advance of demand for our tests. Our current and future expense levels are to a large extent fixed and are largely based on our investment plans and our estimates of future revenue. Because the timing and amount of revenue from our tests is difficult to forecast, when revenue does not meet our expectations, we may not be able to adjust our spending promptly or reduce our spending to levels commensurate with our revenue. Even if we are able to successfully scale our infrastructure and operations, we cannot assure you that demand for our tests will increase at levels consistent with the growth of our infrastructure. If we fail to generate demand commensurate with this growth or if we fail to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition and results of operations could be adversely affected.

If we are not able to continue to generate substantial demand of our tests, our commercial success will be negatively affected.

Our business model assumes that we will be able to generate significant test volume, and we may not succeed in continuing to drive clinical adoption of our test to achieve sufficient volumes. Inasmuch as detailed genetic data from broad-based testing panels such as our tests have only recently become available at relatively affordable prices, the continued pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes. Given the substantial amount of additional information available from a broad-based testing panel such as ours, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate further demand for our tests, we will need to continue to make clinicians aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. Because broad-based testing panels are relatively new, it may be more difficult or take more time for us to expand clinical adoption of our assay beyond our current customer base. In addition, clinicians in other areas of medicine may not adopt genetic testing for hereditary disease as readily as it has been adopted in hereditary cancer and our efforts to sell our tests to clinicians outside of oncology may not be successful. A lack of or delay in clinical acceptance of broad-based panels such as our tests would negatively impact sales and market acceptance of our tests and limit our revenue growth and potential profitability. Genetic testing is expensive and many potential customers may be sensitive to pricing. In addition, potential customers may not adopt our tests if adequate reimbursement is not available, or if we are not able to maintain low prices relative to our competitors. Also, we plan to introduce patient-initiated testing in 2019, in which we will facilitate the ordering of our genetic tests through an online network of physicians. Since we have limited experience directly marketing to patients, we may not be successful in increasing demand for our tests through this new channel. Patient-initiated testing may also be perceived negatively by our existing customer base of clinicians and genetic counselors, in which case our core business could be harmed.

If we are not able to generate demand for our tests at sufficient volume, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition and results of operations could be materially harmed.

Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.

Our success depends on our ability to provide reliable, high-quality tests that incorporate rapidly evolving information about the role of genes and gene variants in disease and clinically relevant outcomes associated with those variants. Errors, such as failure to detect genomic variants with high accuracy, or mistakes, such as failure to identify, or incompletely or incorrectly identifying, gene variants or their significance, could have a significant adverse impact on our business.

Hundreds of genes can be implicated in some disorders, and overlapping networks of genes and symptoms can be implicated in multiple conditions. As a result, a substantial amount of judgment is required in order to interpret testing results for an individual patient and to develop an appropriate patient report. We classify variants in accordance with published guidelines as benign, likely benign, variants of uncertain significance, likely pathogenic or pathogenic, and these guidelines are subject to change. In addition, it is our practice to offer support to clinicians and geneticists ordering our tests regarding which genes or panels to order as well as interpretation of genetic variants. We also rely on clinicians to interpret what we report and to incorporate specific information about an individual patient into the physician's treatment decision.

The marketing, sale and use of our genetic tests could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on, information we provide to clinicians or geneticists, and lead to claims against us if someone were to allege that a test failed to perform as it was designed, if we failed to correctly interpret the test results, or if the ordering physician were to misinterpret test results or improperly rely on them when making a clinical decision. In addition, our entry into the reproductive health testing market exposes us to increased liability. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain liability insurance, including for errors and omissions, we cannot assure you that such insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests. The occurrence of any of these events could have an adverse effect on our reputation and results of operations.

Our industry is subject to rapidly changing technology and new and increasing amounts of scientific data related to genes and genetic variants and their role in disease. Our failure to develop tests to keep pace with these changes could make us obsolete.

In recent years, there have been numerous advances in methods used to analyze very large amounts of genomic information and the role of genetics and gene variants in disease and treatment therapies. Our industry has and will continue to be characterized by rapid technological change, increasingly larger amounts of data, frequent new testing service introductions and evolving industry standards, all of which could make our tests obsolete. Our future success will also depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. Our tests could become obsolete and our business adversely affected unless we continually update our offerings to reflect new scientific knowledge about genes and genetic variations and their role in diseases and treatment therapies.

Our success will depend in part on our ability to generate sales using our internal sales team and through alternative marketing strategies.

We may not be able to market or sell our current tests and any future tests we may develop effectively enough to drive demand sufficient to support our planned growth. We currently sell our tests primarily through our internal sales force. Historically, our sales efforts have been focused primarily on hereditary cancer and more recently, on reproductive health. Our efforts to sell our tests to clinicians outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. We significantly increased the size of our sales force in 2017, 2018, and early 2019. Our future sales will also depend in large part on our ability to develop and substantially expand awareness of our company and our tests through alternative strategies including through education of key opinion leaders, through social media-related and online outreach, education and marketing efforts, and through focused channel partner strategies designed to drive

demand for our tests. We also plan to increase our consumer advertising in connection with our introduction of patient-initiated testing in 2019, which could be costly. We have limited experience implementing these types of marketing efforts. We may not be able to drive sufficient levels of revenue using these sales and marketing methods and strategies necessary to support our planned growth, and our failure to do so could limit our revenue and potential profitability.

Outside the United States we use a limited number of distributors to assist with sales, logistics, education and customer support. Sales practices utilized by our distributors that are locally acceptable may not comply with sales practices standards required under U.S. laws that apply to us, which could create additional compliance risk. If our sales and marketing efforts are not successful outside the United States, we may not achieve significant market acceptance for our tests outside the United States, which could adversely impact our business.

Impairment in the value of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.

We record goodwill and intangible assets at fair value upon the acquisition of a business. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired. Goodwill and indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of a reporting unit could result in an impairment of goodwill or intangible assets and, in turn, a charge to net income. Any such charges could have a material adverse effect on our results of operations or financial condition.

We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments, materials and services, and we may not be able to find replacements or immediately transition to alternative suppliers.

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Illumina, Inc., Integrated DNA Technologies Incorporated, Qiagen N.V., Roche Holdings Ltd. and Twist Bioscience Corporation for certain laboratory substances used in the chemical reactions incorporated into our processes, which we refer to as reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We do not have short- or long-term agreements with most of our suppliers, and our suppliers could cease supplying these materials and equipment at any time, or fail to provide us with sufficient quantities of materials or materials that meet our specifications. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations could impact our supply chain and laboratory operations as well as our ability to conduct our tests, and it could take a substantial amount of time to integrate replacement equipment into our laboratory operations. We also rely on a subsidiary of Illumina, Verinata Health, Inc., to perform non-invasive prenatal screening, or NIPS, testing on our behalf. In the event of any disruption or termination of these services by Verinata, it may be difficult to find a replacement NIPS offering, which could harm our business, financial condition, results of operation and reputation.

We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot assure you that we will be able to secure alternative equipment, reagents and other materials, and bring such equipment, reagents and materials on line and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, we cannot assure you that replacement sequencers and associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business, financial condition, results of operations and reputation could be adversely affected.

If our laboratories in California become inoperable due to disasters or for any other reason, we will be unable to perform our tests and our business will be harmed.

We perform all of our tests at our production facilities in San Francisco and Irvine, California. Our laboratories and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use. Our laboratories may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our tests for some period of time. This risk is especially high for us since we perform the substantial majority of our tests at our San Francisco laboratory, which is located in an active seismic region, and we do not have a redundant facility to perform the same tests in the event our San Francisco laboratory is inoperable. The inability to perform our tests or the backlog that could develop if our laboratories are inoperable for even a short period of time may result in the loss of customers or harm our reputation. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

The loss of any member or change in structure of our senior management team could adversely affect our business.

Our success depends in large part upon the skills, experience and performance of members of our executive management team and others in key leadership positions. The efforts of these persons will be critical to us as we continue to develop our technologies and test processes and focus on scaling our business. If we were to lose one or more key executives, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. All of our executives and employees are at-will, which means that either we or the executive or employee may terminate their employment at any time. We do not carry key man insurance for any of our executives or employees. In addition, we do not have a long-term retention agreement in place with our president and chief executive officer.

Development of new tests is a complex process, and we may be unable to commercialize new tests on a timely basis, or at all.

We cannot assure you that we will be able to develop and commercialize new tests on a timely basis. Before we can commercialize any new tests, we will need to expend significant funds in order to:

- conduct research and development;
- further develop and scale our laboratory processes; and
- further develop and scale our infrastructure to be able to analyze increasingly larger and more diverse amounts of data.

Our testing service development process involves risk, and development efforts may fail for many reasons, including:

- failure of any test to perform as expected;
- lack of validation or reference data; or
- failure to demonstrate utility of a test.

As we develop tests, we will have to make significant investments in development, marketing and selling resources. In addition, competitors may develop and commercialize competing tests faster than we are able to do so.

Changes in financial accounting standards may cause adverse and unexpected revenue fluctuations and affect our reported results of operations.

We prepare our financial statements in accordance with U.S. GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting principles. Changes in these accounting standards or practices may have a significant effect on our results of operations. For example, in May 2014, the Financial Accounting Standards Boards, or FASB, issued Accounting Standards Update 2014-09, "Revenue from Contracts from Customers (Topic 606)," which superseded most existing revenue recognition guidance. We implemented Topic 606 effective January 1, 2018. Please see Note 2, "Summary of significant accounting policies" in the Notes to Consolidated Financial Statements for more information.

From inception through December 2017, we recognized revenue principally when cash was received. Under Topic 606 we now generally recognize revenue on an accrual basis. Accrual amounts are recognized based on estimates of the consideration that we expect to receive and such estimates will be updated and subsequently recorded until fully settled. Adjustments to these estimates may cause fluctuations in our revenue, and may have a material adverse effect on our revenue and our results of operations.

We depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process and drug metabolism, our clinical report optimization systems, our customer-facing web-based software, our customer reporting, our Invitae Family History Tool, PIN, and CancerGene Connect platform. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, customer relationship management, regulatory compliance and other infrastructure operations. In addition, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design, and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, and general administrative activities, including financial reporting.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to clinicians, billing payers, processing reimbursement appeals, handling physician or patient inquiries, conducting research and development activities, and managing the administrative and financial aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and results of operations.

Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions in our business and operations. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests.

Genetic testing has raised ethical, legal and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genomic tests even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests, either of which could have an adverse effect on our business, financial condition or results of operations.

Our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

We currently have a limited number of distribution arrangements in several countries outside of the United States. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;

- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if we do not to conduct our tests locally;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our international operations and, consequently, our revenue and results of operations.

In addition, applicable export or import laws and regulations such as prohibitions on the export of samples imposed by countries outside of the United States, or international privacy or data restrictions that are different or more stringent than those of the United States, may require that we build additional laboratories or engage in joint ventures or other business partnerships in order to offer our tests internationally in the future. Any such restrictions would impair our ability to offer our tests in such countries and could have an adverse effect on our business, financial condition and results of operations.

Changes in U.S. tax laws could adversely impact us.

On December 22, 2017, President Trump signed The Tax Cuts and Jobs Act, the Tax Act, into law. The Tax Act contains significant changes to U.S. federal corporate income taxation, including reduction of the corporate tax rate from 35% to 21% for U.S. taxable income, resulting in a one-time remeasurement of deferred taxes to reflect their value at a lower tax rate of 21%, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, deemed repatriation, resulting in one-time taxation of offshore earnings at reduced rates, elimination of U.S. tax on foreign earnings (subject to certain exceptions), and immediate deductions for certain new investments instead of deductions for depreciation expense over time. Although the Tax Act was generally effective January 1, 2018, GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017. As a result of the lower corporate tax rate enacted as part of the Tax Act, we recorded a provisional estimate to reduce deferred tax assets by \$48.8 million. The reduction in deferred tax assets was offset by a corresponding reduction in our valuation allowance resulting in no net impact to tax expense. We have determined that the adjustment to the deferred tax assets and valuation allowance recorded in connection with the remeasurement of certain deferred tax assets and liabilities is a reasonable estimate at December 31, 2017. In the fourth quarter of 2018, we completed our analysis to determine the effect of the Tax Act and no material adjustments were recognized as of December 31, 2018.

Risks related to government regulation

If the FDA regulates our tests as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.

We provide our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and state law, respectively).

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth

a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. Subsequently, on January 13, 2017, the FDA published a “discussion paper” in which it outlined a substantially revised “possible approach” to the oversight of LDTs. In December 2018, a draft bill titled the “Verifying Accurate Leading-edge IVCT Development Act of 2018”, or VALID Act, was released for discussion. The draft bill proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test, or IVCT, category of regulated products, which includes LDTs, and a regulatory structure under the FDA. As proposed, the draft bill grandfathers many existing tests from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (e.g., registration and notification, adverse event reporting). We cannot predict if this draft bill will be enacted in its current (or any other) form and cannot quantify the effect of this draft bill on our business.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time-to-time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time.

If the FDA ultimately regulates certain LDTs (either as medical devices or as part of a new stand-alone regulatory category for IVCTs), whether via individualized enforcement action, or more generally, as outlined in final guidance or final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition and results of operations.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

In addition, in November 2013, the FDA issued final guidance regarding the distribution of products labeled for research use only. Certain of the reagents and other products we use in our tests are labeled as research use only products. Certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

If we fail to comply with federal, state and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers, for our tests. We have current CLIA certifications to conduct our tests at our laboratories in San Francisco and Irvine, California. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories.

We are also required to maintain licenses to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratories in San Francisco and Irvine, including the training and skills required of personnel and quality control. We also maintain out-of-state laboratory licenses to conduct testing on specimens from Maryland, New York, Pennsylvania and Rhode Island.

In addition to having laboratory licenses in New York, our clinical reference laboratories are approved on test-specific bases by the New York State Department of Health, or NYDOH. Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of samples necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and cancellation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

The College of American Pathologists, or CAP, maintains a clinical laboratory accreditation program. CAP asserts that its program is "designed to go well beyond regulatory compliance" and helps laboratories achieve the highest standards of excellence to positively impact patient care. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. We have CAP accreditations for our laboratories. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions;
- amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators and expand vicarious liability, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or recommend purchasing, leasing or ordering, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;
- the federal physician self-referral law, known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity unless an exception applies, and prohibits an entity from billing for designated health services furnished pursuant to a prohibited referral;
- the federal false claims law, which impose liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

- the HIPAA fraud and abuse provisions, which created new federal criminal statutes that prohibit, among other things, defrauding health care benefit programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payers; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance may also be subject to governmental review. The growth of our business and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including administrative, civil and criminal penalties, damages, fines, individual imprisonment, exclusion from participation in Federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Healthcare policy changes, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition, results of operations and cash flows.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other things, the Affordable Care Act requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, and applied to sales of taxable medical devices from January 1, 2013 through December 31, 2015. The medical device tax has been suspended for 2016 through 2019, but is scheduled to return beginning in 2020. It is unclear at this time when, or if, the provision of our LDTs will trigger the medical device tax if the FDA ends its policy of general enforcement discretion and regulates certain LDTs as medical devices. It is possible, however, that this tax will apply to some or all of our tests or tests that are in development.

Many of the Current Procedure Terminology, or CPT, procedure codes that we use to bill our tests were revised by the American Medical Association, effective January 1, 2013. Moreover, effective January 1, 2015, the AMA released several new codes to report genomic sequencing procedures. In a final determination under the Medicare Clinical Laboratory Fee Schedule, or CLFS, published in November 2014, CMS set the 2015 payment rate for these codes by the gap-fill process. Under the gap-fill process, local Medicare Administrative Contractors, or MACs, establish rates for those codes that each MAC believes meet the criteria for Medicare coverage and considering laboratory charges and discounts to charges, resources, amounts paid by other payers for the tests, and amounts paid by the MAC for similar tests. In 2015, gap-filled payment rates were established for some, but not all, of the above-described codes. For those codes for which local gap-filled rate(s) were established in 2015, a national limitation amount for Medicare was established for 2016. Codes for which local gap-filled rates were not established in 2015 were priced by the local MACs in 2016 insofar as an individual MAC determines that such codes should be covered. Where available, the national limitation amount serves as a cap on the Medicare and Medicaid payment rates for a test procedure.

The AMA also released several CPT codes effective January 1, 2016 that may be appropriate to report certain of our tests. In a November 2015 final determination, CMS set the calendar year 2016 CLFS payment rate for these new codes by the gap-fill process. CMS and the local MACs went through the gap-fill process in 2016 and announced final gap-filled rates for 2017 on September 30, 2016. The calendar year 2017 national limitation amounts for certain codes were significantly less than the rates at which we have historically offered our tests.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under the final rule that implements PAMA, which was promulgated by CMS in June 2016, clinical laboratories must report to CMS private payer rates beginning in 2017 and every three years thereafter for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests and every year for advanced diagnostic laboratory tests.

We do not believe that our tests meet the definition of advanced diagnostic laboratory tests, but in the event that we seek designation for one or more of our tests as an advanced diagnostic laboratory test and the tests are determined by CMS to meet these criteria or new criteria developed by CMS, we would be required to report private payer data for those tests annually. Otherwise, we will be required to report private payer rates for our tests on an every three years basis. Laboratories that fail to timely report the required payment information may be subject to substantial civil money penalties.

As set forth in the PAMA final rule, for tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are paid based upon these reported private payer rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the cross-walk or gap-fill methodology, similar to prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test. The payment rates calculated under PAMA went into effect starting January 1, 2018. Where applicable, reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020 and to 15% per test per year in each of 2021 through 2023 (following a second round of private payer rate reporting in 2020 to establish rates for 2021 through 2023).

PAMA also authorized the adoption of new, temporary billing codes and/or unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The CPT® Editorial Panel approved a proposal to create a new section of billing codes to facilitate implementation of this section of PAMA, but it is unclear how these codes would apply to our tests.

In March 2018, CMS published a final national coverage determination, or NCD, for next generation sequencing, or NGS, tests for patients with advanced cancer. The final NCD establishes full coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays when offered for their FDA-approved or FDA-cleared use(s), ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer) who have not have previously been tested with the same test for the same primary diagnosis of cancer or are seeking repeat testing for a new primary cancer diagnosis, and have decided to seek further cancer treatment. The final NCD also gives MACs the authority to establish local coverage for NGS-based assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It is unclear, however, whether MACs retain the authority to establish local coverage for NGS-based tests provided for patients with cancer that do not meet the above-referenced criteria - e.g., patients with earlier stage cancers or patients with a personal history of cancer - or if such tests are nationally non-covered under the NCD. If CMS interprets the final NCD to exclude coverage for patients with earlier stage cancers or personal history of cancer, MACs will no longer have discretion to cover our current tests when offered to such patients, notwithstanding historical Medicare coverage for such tests. An interpretation of the NCD that results in Medicare non-coverage for our current and future assays would have significant negative impact on our business, financial condition and results of operations.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. For instance, the payment reductions imposed by the Affordable Care Act and the expansion of the federal and state governments' role in the U.S. healthcare industry as well as changes to the reimbursement amounts paid by payers for our tests and future tests or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Notably, Congress enacted legislation in 2017 that eliminates the Affordable Care Act's "individual mandate" beginning in 2019, which may significantly impact the number of covered lives participating in exchange plans. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would increase our billing and collecting costs and decrease our revenue.

If we use hazardous materials in a manner that causes injury, we could be liable for resulting damages.

Our activities currently require the use of hazardous chemicals and biological material. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. In 2018, we decommissioned our laboratory in Cambridge, Massachusetts; however, we could be held liable for any damages resulting from our prior use of hazardous chemicals and biological materials at this facility. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

We could be adversely affected by violations of the FCPA and other worldwide anti-bribery laws.

We are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We use a limited number of independent distributors to sell our tests internationally, which requires a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

Risks related to our intellectual property

Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation may require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price.

Our commercial success will depend in part on our avoiding infringement of patents and proprietary rights of third parties, including for example the intellectual property rights of competitors. As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests, and enter new markets, competitors might claim that our tests infringe or misappropriate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. Our activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We may be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, regardless of merit, could cause us to incur substantial expenses and be a substantial diversion of our employee resources. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our business and stock price. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, possibly including treble damages and attorneys' fees if we are found to have willfully infringed patents; (2) obtain one or more licenses, which may not be available on commercially reasonable terms (if at all); (3) pay royalties; and/or (4) redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, all of which could have a material adverse impact on our cash position and business and financial condition.

If licenses to third-party intellectual property rights are or become required for us to engage in our business, we may be unable to obtain them at a reasonable cost, if at all. Even if such licenses are available, we could incur

substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in the introduction of tests while we attempt to develop alternatives. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing tests, which could materially affect our ability to grow and thus adversely affect our business and financial condition.

Developments in patent law could have a negative impact on our business.

Although we view current U.S. Supreme Court precedent to be aligned with our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts (such as patient genetic data) and an understanding of that fact's implications (such as a patient's risk of disease associated with certain genetic variations) should not be patentable, it is possible that subsequent determinations by the U.S. Supreme Court or other federal courts could limit, alter or potentially overrule current law. Moreover, from time to time the U.S. Supreme Court, other federal courts, the United States Congress or the U.S. Patent and Trademark Office, or USPTO, may change the standards of patentability, and any such changes could run contrary to, or otherwise be inconsistent with, our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts and an understanding of that fact's implications should not be patentable, which could result in third parties newly claiming that our business practices infringe patents drawn from categories of patents which we currently view to be invalid as directed to unpatentable subject matter.

Our inability to effectively protect our proprietary technologies, including the confidentiality of our trade secrets, could harm our competitive position.

We currently rely upon trade secret protection and copyright, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, and to a limited extent patent protection, to protect our confidential and proprietary information. Although our competitors have utilized and are expected to continue utilizing similar methods and have aggregated and are expected to continue to aggregate similar databases of genetic testing information, our success will depend upon our ability to develop proprietary methods and databases and to defend any advantages afforded to us by such methods and databases relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our methods and databases and thereby erode any competitive advantages we may have.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. In this regard, we have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, we expect that potential patent coverage we may obtain will not be sufficient to prevent substantial competition. In this regard, we believe it is probable that others will independently develop similar or alternative technologies or design around those technologies for which we may obtain patent protection. In addition, any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. Questions as to inventorship or ownership may also arise. Any finding that our patents or applications are unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. If we initiate lawsuits to protect or enforce our patents, or litigate against third party claims, which would be expensive, and, if we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel.

We expect to rely primarily upon trade secrets and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. Among other things, we seek to protect our trade secrets and confidential information by entering into confidentiality agreements with employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees and consultants will provide meaningful protection for our trade secrets and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Accordingly, there also can be no assurance that our trade secrets will not otherwise become known or be independently developed by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks related to being a public company

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and the New York Stock Exchange, or NYSE, impose a number of requirements on public companies, including with respect to corporate governance practices. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In addition, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, enacted in 2010, includes significant corporate governance and executive-compensation-related provisions. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. If these requirements divert the attention of our management and personnel from other aspects of our business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, these rules and regulations applicable to public companies substantially increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time-consuming and costly. It may also be more expensive for us to obtain director and officer liability insurance.

If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

We are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not

detect errors on a timely basis and our financial statements may be materially misstated. We have compiled the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We need to maintain and enhance these processes and controls as we grow and we have required, and may continue to require, additional personnel and resources to do so.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal controls, our management will be unable to conclude that our internal control over financial reporting is effective. Moreover, when we are no longer an emerging growth company, as described below, our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or when we are no longer an emerging growth company, if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in the restatement of our financial results in the future.

We are an emerging growth company and have elected to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an emerging growth company, as defined under the Securities Act. We will remain an emerging growth company until December 31, 2020, although if our revenue exceeds \$1.07 billion in any fiscal year before that time, we would cease to be an emerging growth company as of the end of that fiscal year. In addition, if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our second fiscal quarter of any fiscal year before the end of that five-year period, we would cease to be an emerging growth company as of December 31 of that year. As an emerging growth company, we have chosen to take advantage of exemptions from various reporting requirements applicable to certain other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced financial statement and financial-related disclosures, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirement of holding a nonbinding advisory vote on executive compensation and obtaining stockholder approval of any golden parachute payments not previously approved by our stockholders. We cannot predict whether investors will find our common stock less attractive because we have chosen to rely on any of these exemptions. If investors find our common stock less attractive as a result of any choices to reduce future disclosure we may make, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks related to our common stock

Our stock price is volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

The trading price of our common stock is volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated fluctuations in our operating results;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our stock;
- our focus on long-term goals over short-term results;
- the timing of our investments in the growth of our business;
- actual or anticipated changes in regulatory oversight of our business;

- additions or departures of key management or other personnel;
- disputes or other developments related to our intellectual property or other proprietary rights, including litigation;
- changes in reimbursement by current or potential payers;
- general economic and market conditions; and
- issuances of significant amounts of our common stock.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock, change their price targets, issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

At December 31, 2018, our total gross deferred tax assets were \$131.9 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, or other future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. In addition, the Tax Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Also, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, our 2018 Note Purchase Agreement limits our ability to pay dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 20,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our chairman of the board or our chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum; and
- require a super-majority of votes to amend certain of the above-mentioned provisions as well as to amend our bylaws generally.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law; or
- any action asserting a claim against us governed by the internal affairs doctrine.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

ITEM 1B. Unresolved Staff Comments.

None.

ITEM 2. Properties.

Our headquarters and main production facility is located in San Francisco, California, where we currently lease and occupy approximately 103,000 square feet of laboratory and office space. The lease for this facility expires in July 2026 and we may renew the lease for an additional ten years.

Our subsidiary Good Start leases approximately 67,000 square feet of laboratory and office space in Massachusetts, and our subsidiary CombiMatrix leases approximately 12,000 square feet of laboratory and office space in Irvine, California. We also lease additional facilities in Palo Alto and Oakland, California.

We believe that our facilities are adequate for our current needs and that additional space will be available on commercially reasonable terms if required.

ITEM 3. Legal Proceedings.

We are not a party to any material legal proceedings on the date of this report. We may from time to time become involved in legal proceedings arising in the ordinary course of business, and the resolution of any such claims could be material.

ITEM 4. Mine Safety Disclosure.

Not applicable.

Executive Officers of the Registrant

The names of our executive officers and other corporate officers, and their ages as of February 28, 2019, are as follows:

Name	Age	Position
Executive officers		
Randal W. Scott, Ph.D.	61	Executive Chairman and Director
Sean E. George, Ph.D.	45	President, Chief Executive Officer, Director and Co-Founder
Lee Bendekgey	61	Chief Operating Officer and Secretary
Thomas R. Brida	48	General Counsel
Shelly D. Guyer	58	Chief Financial Officer
Robert L. Nussbaum, M.D.	69	Chief Medical Officer
Katherine A. Stueland	43	Chief Commercial Officer

Randal W. Scott, Ph.D. has served as our Executive Chairman since January 2017 and as a director since 2010. From August 2012 through January 2017, Dr. Scott served as our Chief Executive Officer. From 2000 through August 2012, Dr. Scott held a number of positions at Genomic Health, Inc., a publicly held genomic information company which he co-founded in 2000, most recently serving as the Chief Executive Officer of a wholly-owned subsidiary of Genomic Health, and as a director. Dr. Scott also served as Executive Chairman of the Board of Genomic Health from January 2009 until March 2012 and as Chairman of the Board and Chief Executive Officer from August 2000 until December 2008. Dr. Scott was a founder of Incyte Corporation, which at the time was a genomic information company, and served in various roles from 1991 through 2000, including Chairman of the Board, President and Chief Scientific Officer. Dr. Scott holds a B.S. in Chemistry from Emporia State University and a Ph.D. in Biochemistry from the University of Kansas.

Sean E. George, Ph.D. is one of our co-founders and has been our President and Chief Executive Officer since January 2017, a position he also held from January 2010 through August 2012. Dr. George also served as our President since August 2012 and he served as our Chief Operating Officer from August 2012 until January 2017. He has also served as a director since January 2010. Prior to co-founding Invitae, Dr. George served as Chief Operating Officer from 2007 to November 2009 at Navigenics, Inc., a personalized medicine company. Previously, he served as Senior Vice President of Marketing and Senior Vice President, Life Science Business at Affymetrix, Inc., a provider of life science and molecular diagnostic products, as well as Vice President, Labeling and Detection Business at Invitrogen Corporation, a provider of tools to the life sciences industry, during his tenure there from 2002 to 2007. Dr. George holds a B.S. in Microbiology and Molecular Genetics from the University of California Los Angeles, an M.S. in Molecular and Cellular Biology from the University of California Santa Barbara, and a Ph.D. in Molecular Genetics from the University of California Santa Cruz.

Lee Bendekgey has served as our Chief Operating Officer since June 2017. Mr. Bendekgey also served as our Chief Financial Officer from November 2013 to June 2017 and as our General Counsel from November 2013 through January 2017. Prior to joining our company, he was the General Counsel of DNAnexus, Inc., a cloud-based genome informatics and data management company, from September 2011 to October 2013. From March 2009 until September 2011, Mr. Bendekgey pursued personal interests. Prior to that, he was Chief Financial Officer and General Counsel for Nuvelo, Inc., a biopharmaceutical company, from July 2004 to March 2009. Mr. Bendekgey also served as General Counsel and Chief Financial Officer for Incyte Corporation from 1998 to 2004. Mr. Bendekgey holds a B.A. in French and Political Science from Kalamazoo College and a J.D. from Stanford Law School.

Thomas R. Brida has served as our General Counsel since January 2017. Mr. Brida also served as our Deputy General Counsel from January 2016 to January 2017. Prior to joining Invitae, he was Associate General Counsel at Bio-Rad Laboratories, a life science research and clinical diagnostics manufacturer, from January 2004 to January 2016. He holds a B.A. from Stanford University and a J.D. from the U.C. Berkeley School of Law.

Shelly D. Guyer has served as our Chief Financial Officer since June 2017. Ms. Guyer served as Chief Financial Officer of Veracyte, Inc., a genomic diagnostics company, from April 2013 to December 2016 and served as Veracyte's Secretary from April 2013 to March 2014. Previously, she served as Chief Financial Officer and Executive Vice President of Finance and Administration of iRhythm Technologies, Inc., a digital healthcare company, from April 2008 to December 2012. From March 2006 to August 2007, Ms. Guyer served as Vice President of Business Development and Investor Relations of Nuvelo, Inc., a biopharmaceutical company. Prior to joining Nuvelo, Ms. Guyer worked at J.P. Morgan Securities and its predecessor companies for over 17 years, serving in a variety of roles including in healthcare investment banking. Ms. Guyer holds an A.B. in Politics from Princeton University and an M.B.A. from the Haas School of Business at the University of California Berkeley.

Robert L. Nussbaum, M.D. has served as our Chief Medical Officer since August 2015. From April 2006 to August 2015, he was chief of the Division of Genomic Medicine at UCSF Health where he also held leadership roles in the Cancer Genetics and Prevention Program beginning in January 2009 and the Program in Cardiovascular Genetics beginning in July 2007. From April 2006 to August 2015, he served as a member of the UCSF Institute for Human Genetics. Prior to joining UCSF Health, Dr. Nussbaum was chief of the Genetic Disease Research Branch of the National Human Genome Research Institute, one of the National Institutes of Health, from 1994 to 2006. He is a member of the National Academy of Medicine and a fellow at the American Academy of Arts and Sciences. Dr. Nussbaum is a board-certified internist and medical geneticist who holds a B.S. in Applied Mathematics from Harvard College and an M.D. from Harvard Medical School in the Harvard-MIT joint program in Health Sciences and Technology. He completed his residency in internal medicine at Barnes-Jewish Hospital and a fellowship in medical genetics at the Baylor College of Medicine.

Katherine A. Stueland has served as our Chief Commercial Officer since October 2016. From January 2014 to October 2016, she served as our head of communications and investor relations. Prior to joining Invitae, Ms. Stueland was a Principal at Vivo Communications, a healthcare communications company, from January 2013 to December 2013. Previously, she served as Vice President, Communications and Investor Relations at Dendreon Corporation, a biotechnology company. Ms. Stueland holds a B.S. in English Literature from Miami University in Ohio.

PART II

ITEM 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been publicly traded on the New York Stock Exchange under the symbol “NVTA” since February 12, 2015. Prior to that time, there was no public market for our common stock.

As of February 22, 2019, there were 48 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

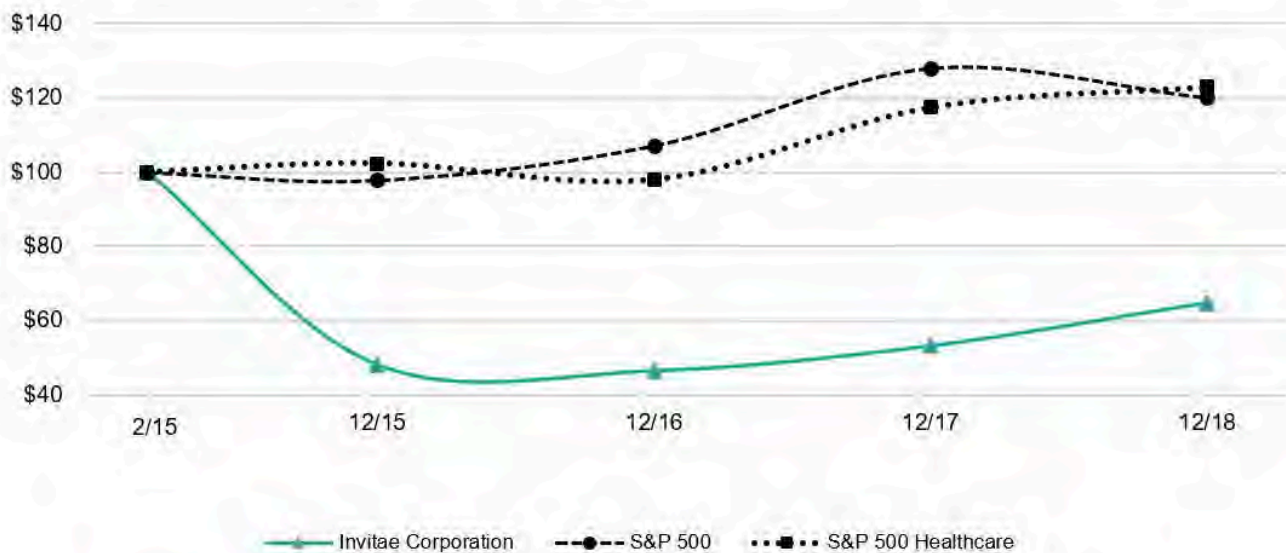
Dividend policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. In addition, our 2018 Note Purchase Agreement limits our ability to pay dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Stock performance graph

The following information shall not be deemed to be soliciting material or to be filed with the SEC, or subject to Regulations 14A or 14C under the Securities Exchange Act of 1934 (“Exchange Act”) or to the liabilities of Section 18 of the Exchange Act nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

Comparison of Historical Cumulative Total Return Among Invitae Corporation, the S&P 500 Index and the S&P 500 Healthcare Index(*)



(*) The above graph shows the cumulative total stockholder return of an investment of \$100 in cash from February 12, 2015 (the date our common stock commenced trading on the New York Stock Exchange) through December 31, 2018 for: (i) our common stock; (ii) the S&P 500 Index; and (iii) the S&P 500 Healthcare Index. All values assume reinvestment of the full amount of all dividends. The comparisons in the table are required by the SEC and are not intended to be forecasts or indicative of future stockholder returns.

	2/12/2015	12/31/2015	12/31/2016	12/31/2017	12/31/2018
Invitae Corporation	\$ 100.00	\$ 48.15	\$ 46.57	\$ 53.26	\$ 64.87
S&P 500	\$ 100.00	\$ 97.87	\$ 107.20	\$ 128.02	\$ 120.03
S&P 500 Healthcare Index	\$ 100.00	\$ 102.41	\$ 97.94	\$ 117.53	\$ 123.05

ITEM 6. Selected Financial Data.

The information set forth below should be read together with “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this report. The selected consolidated balance sheet data at December 31, 2018 and 2017 and the selected consolidated statements of operations data for each of the years ended December 31, 2018, 2017, and 2016 have been derived from our audited consolidated financial statements that are included elsewhere in this report. The selected consolidated balance sheet data at December 31, 2016, 2015 and 2014 and the selected consolidated statement of operations data for the years ended December 31, 2015 and 2014 have been derived from our audited consolidated financial statements not included in this report. Historical results are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
	2018 ⁽¹⁾	2017 ⁽²⁾	2016	2015 ⁽³⁾	2014
	(In thousands except per share data)				
Consolidated Statements of Operations Data					
Test revenue	\$ 144,560	\$ 65,169	\$ 24,840	\$ 8,378	\$ 1,604
Other revenue	3,139	3,052	208	—	—
Total revenue	147,699	68,221	25,048	8,378	1,604
Costs and operating expenses:					
Cost of revenue ⁽⁴⁾	80,105	50,142	27,878	16,523	5,624
Research and development ⁽⁴⁾	63,496	46,469	44,630	42,806	22,063
Selling and marketing ⁽⁴⁾	74,428	53,417	28,638	22,479	8,669
General and administrative ⁽⁴⁾	52,227	39,472	24,085	16,047	12,600
Total costs and operating expenses	270,256	189,500	125,231	97,855	48,956
Loss from operations	(122,557)	(121,279)	(100,183)	(89,477)	(47,352)
Other income (expense), net	(2,568)	(303)	348	(94)	(79)
Interest expense	(7,030)	(3,654)	(421)	(211)	(61)
Net loss before taxes	(132,155)	(125,236)	(100,256)	(89,782)	(47,492)
Income tax benefit	(2,800)	(1,856)	—	—	—
Net loss	\$ (129,355)	\$ (123,380)	\$ (100,256)	\$ (89,782)	\$ (47,492)
Net loss per share, basic and diluted ⁽⁵⁾	\$ (1.94)	\$ (2.65)	\$ (3.02)	\$ (3.18)	\$ (56.14)
Shares used in computing net loss per share, basic and diluted	66,747	46,512	33,176	28,213	846

As of December 31,

	2018 ⁽¹⁾	2017 ⁽²⁾	2016	2015 ⁽³⁾	2014
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(In thousands)

Consolidated Balance Sheet Data:

Cash and cash equivalents	\$ 112,158	\$ 12,053	\$ 66,825	\$ 73,238	\$ 107,027
Working capital	129,127	53,294	87,047	120,433	102,020
Total assets	282,959	211,078	130,651	156,676	128,778
Capital lease obligations	3,312	5,412	1,575	3,164	3,535
Debt	74,477	39,084	12,102	7,040	—
Total liabilities	121,120	89,284	31,577	18,300	10,049
Convertible preferred stock	—	—	—	—	202,305
Accumulated deficit	(516,712)	(398,598)	(275,218)	(174,962)	(85,180)
Total stockholders' equity (deficit)	161,839	121,794	99,074	138,376	(83,576)

(1) On January 1, 2018, we adopted ASC Topic 606 using the modified retrospective transition method. Prior period amounts are presented as originally reported based upon the accounting standards in effect for those periods.

(2) In 2017, we completed the acquisition of four businesses which are included in our selected consolidated financial data as of each acquisition date.

(3) Upon the closing of our initial public offering in February 2015, 141,131,524 shares of convertible preferred stock then outstanding converted into 23,521,889 shares of common stock.

(4) Includes employee stock-based compensation as follows:

Year Ended December 31,

	2018	2017	2016	2015	2014
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(In thousands)

Cost of revenue	\$ 2,960	\$ 2,093	\$ 1,353	\$ 368	\$ 102
Research and development	7,017	6,158	4,976	1,545	382
Selling and marketing	4,887	3,956	1,709	688	216
General and administrative	5,986	7,014	2,661	876	271
Total stock-based compensation	\$ 20,850	\$ 19,221	\$ 10,699	\$ 3,477	\$ 971

(5) See Note 2, "Summary of significant accounting policies," and Note 13, "Net loss per share," in our audited consolidated financial statements included elsewhere in this report for an explanation of the calculations of our basic and diluted net loss per share.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes included in Item 8 of this report. Historic results are not necessarily indicative of future results.

Business overview

We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets. We acquired four businesses in 2017 and in doing so expanded our suite of genome management offerings and completed our entry into prenatal and perinatal genetic testing.

In 2017, we established a leading position in family health genetic information services through the strategic acquisition of reproductive health testing capabilities. In January 2017, we acquired AltaVoice, formerly PatientCrossroads, a patient-centered data company with a global platform for collecting, curating, coordinating and delivering safeguarded data from patients and clinicians. This acquisition was complemented by the acquisition in June 2017 of Ommdom, Inc. and its product, CancerGene Connect, an end-to-end platform for collecting and managing genetic family histories to deliver personalized genetic risk information. In August 2017, we acquired Good Start Genetics, Inc., or Good Start, a molecular diagnostics company focused on preimplantation and carrier screening for inherited disorders. In November 2017, we completed our acquisition of CombiMatrix Corporation (CombiMatrix), a company specializing in prenatal diagnosis, miscarriage analysis and pediatric developmental disorders.

We have experienced rapid growth. For the years ended December 31, 2018, 2017 and 2016, our revenue was \$147.7 million, \$68.2 million and \$25.0 million, respectively and we incurred net losses of \$129.4 million, \$123.4 million and \$100.3 million, respectively. At December 31, 2018, our accumulated deficit was \$516.7 million. We increased our number of employees to 788 at December 31, 2018 from 594 on December 31, 2017. Our sales force grew to 128 at December 31, 2018 from 103 at December 31, 2017. We expect headcount will continue to increase in 2019 as we add staff to support anticipated growth.

Sales of our tests have grown significantly. In 2018, 2017 and 2016, we generated approximately 292,000, 145,000 and 57,000 billable tests, respectively. Through December 31, 2018, approximately 29% of the billable tests we performed have been billable to institutions and patients, and the remainder have been billable to third-party payers. Many of the gene tests on our assays are tests for which private insurers reimburse. However, when we do not have reimbursement policies or contracts with private insurers, our claims for reimbursement may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. Even if we are successful in achieving reimbursement, we may be paid at lower rates than if we were under contract with the third-party payer. When there is not a contracted rate for reimbursement, there is typically a greater coinsurance or copayment requirement from the patient which may result in further delay or decreased likelihood of collection.

We expect to incur operating losses for the near-term future and may need to raise additional capital in order to fund our operations. If we are unable to achieve our revenue growth objectives and successfully manage our costs, we may not be able to achieve profitability.

We believe that the keys to our future growth will be to increase billable test volumes, achieve broad reimbursement coverage for our tests from third-party payers, consistently drive down the price for genetic analysis and interpretation, steadily increase the amount of genetic content we offer, consistently improve the client experience, drive physician and patient utilization of our website for ordering and delivery of results and increase the number of strategic partners working with us to add value for our clients.

Factors affecting our performance

Number of billable tests

The growth in our genetic testing business is tied to the number of tests for which we bill third-party payers, institutions, partners or patients, which we refer to as billable tests. We typically bill for our services following delivery of the billable test report derived from testing samples and interpreting the results. We incur the expenses associated with a test in the period in which the test is processed regardless of when payment is received with respect to that test. We believe the number of billable tests in any period is the most important indicator of the growth in our business, and with time, this will translate into the number of customers we add to the platform and the revenue generated per customer.

Success obtaining and maintaining reimbursement

Our ability to increase the number of billable tests and our revenue will depend in part on our success achieving broad reimbursement coverage and laboratory service contracts for our tests from third-party payers and agreements with institutions and partners. Reimbursement may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary and cost-effective, as well as whether we are in contract, where we get paid more consistently and at higher rates. Because each payer makes its own decision as to whether to establish a policy or enter into a contract to reimburse for our testing services, seeking these approvals is a time-consuming and costly process. In addition, clinicians may decide not to order our tests if the cost of the test is not covered by insurance. Our revenue growth also depends on our ability to successfully promote the adoption of our testing services and expand our base of ordering clinicians. We believe that establishing coverage and obtaining contracts from third-party payers is an important factor in gaining adoption by ordering clinicians. As of December 2018, we have entered in to contracts for laboratory services with payers covering approximately 264 million lives, comprised of Medicare, most national health plans, and Medicaid in 37 states, including California (Medi-Cal), our home state.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements may vary from payer to payer, and it may be time-consuming and require additional resources to meet these requirements. We may also experience delays in or denials of coverage if we do not adequately comply with these requirements. In addition, we have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests, tests provided by companies we acquire and any future tests we may develop. However, if we are not able to continue to obtain and maintain adequate reimbursement from third-party payers and institutions for our testing services and expand the base of clinicians ordering our tests, we may not be able to effectively increase the number of billable tests or our revenue.

Ability to lower the costs associated with performing our tests

Reducing the costs associated with performing our genetic tests is both a near-term focus and a strategic objective of ours. Over the long term, we need to continue to reduce the cost of performing tests by improving the output efficiency of our assays and laboratory processes, modifying our platform-agnostic assays and laboratory processes to use materials and technologies that provide equal or greater quality at lower cost, improving how we manage our materials, porting some tests onto next generation sequencing platforms and negotiating favorable terms for our materials purchases. We also intend to continue to design and implement hardware and software tools that will reduce personnel-related costs for both laboratory and clinical operations/medical interpretation by increasing personnel efficiency and thus lowering labor costs per test.

Ability to expand our genetic content

As we reduce our costs, we intend to continue to expand our test menus by steadily releasing additional genetic content for the same or lower prices per test, ultimately leading to affordable whole genome services. The breadth and flexibility of our offering will be a critical factor in our ability to address new markets for genetic testing services. Both of these will be critical to our ability to continue to grow the volume of billable tests we deliver.

Investment in our business and timing of expenses

We plan to continue to invest in our genetic testing and information management business. We deploy state-of-the-art and costly technologies in our genetic testing services, and we intend to continue to scale our infrastructure, including our testing capacity and information systems. We also expect to incur software development costs as we seek to further automate our laboratory processes and our genetic interpretation and report sign-out procedures, scale our customer service capabilities and expand the functionality of our website. We plan to hire additional personnel as necessary to support anticipated growth, including software engineers, sales and marketing personnel, billing personnel, research and development personnel, medical specialists, biostatisticians and geneticists. We will also incur additional costs related to the expansion of our production facility in San Francisco to accommodate growth. In addition, we expect to incur ongoing expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter, as we focus on building out different aspects of our business.

How we recognize revenue

From inception through December 31, 2017, we recognized revenue principally when cash was received. Effective January 1, 2018, we implemented Financial Accounting Standards Board Accounting Standards Codification Topic 2014-09, *Revenue from Contracts with Customers* ("Topic 606"), using the modified retrospective method. (See Note 3, "Revenue, accounts receivable and deferred revenue" in the Notes to Consolidated Financial Statements included elsewhere in this report.) Prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for those periods. Under Topic 606, we generally recognize revenue on an accrual basis, which is when a customer obtains control of the promised goods or services, typically a test report. Accrual amounts recognized are based on estimates of the consideration that we expect to receive and such estimates will be adjusted and subsequently recorded until fully settled. Changes to such estimates may increase or decrease revenue recognized in future periods. Revenue from our tests may not be equal to billed amounts due to a number of factors, including differences in reimbursement rates, the amounts of patient copayments, the existence of secondary payers and claims denials.

Financial overview

Revenue

We primarily generate revenue from the sale of our tests, which provide the analysis and associated interpretation of the sequencing of parts of the genome. Clients are billed upon delivery of test results to the physician. Our ability to increase our revenue will depend on our ability to increase our market penetration, obtain contracted reimbursement coverage from third-party payers, enter into contracts with institutions and partners, and increase the rate at which we are paid for tests performed.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering test results to clinicians and includes expenses for materials and supplies, personnel-related costs, equipment and infrastructure expenses associated with testing and allocated overhead including rent, equipment depreciation and utilities. Costs associated with performing our test are recorded as the patient's sample is processed. We expect cost of revenue to generally increase in line with the increase in the number of tests we perform. However, we expect that the cost per test will decrease over time due to the efficiencies we expect to gain as test volume increases and from automation and other cost reductions, but it could fluctuate quarter-to-quarter.

Operating expenses

Our operating expenses are classified into three categories: research and development, selling and marketing, and general and administrative. For each category, the largest component is personnel-related costs, which include salaries, employee benefit costs, bonuses, commissions, as applicable, and stock-based compensation expense.

Research and development

Research and development expenses represent costs incurred to develop our technology and future tests. These costs are principally for process development associated with our efforts to expand the number of genes we can evaluate in our tests and with our efforts to lower the cost of performing our test. In addition, we incur process development costs to further develop the software we use to operate our laboratory, analyze the data it generates, process customer orders, deliver reports and automate our business processes. These costs consist of personnel-related costs, laboratory supplies and equipment expenses, consulting costs, amortization of acquired intangibles, and allocated overhead including rent, information technology, equipment depreciation and utilities.

We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to increase as we continue our efforts to develop additional tests, make investments to reduce testing costs and work on scaling the business.

Selling and marketing

Selling and marketing expenses consist of personnel-related costs, client service expenses, advertising and marketing expenses, educational and promotional expenses, market research and analysis, amortization of acquisition-related intangible assets and allocated overhead including rent, information technology, equipment depreciation and utilities. We expect our selling and marketing expenses to significantly increase as we expand our salesforce and increase our advertising.

General and administrative

General and administrative expenses include executive, finance and accounting, billing and collections, legal and human resources functions. These expenses include personnel-related costs, audit and legal expenses, consulting costs, amortization of acquisition-related intangible assets, losses incurred in relation to collaboration agreements and allocated overhead including rent, information technology, equipment depreciation and utilities. We expect our general and administrative expenses to increase at a moderate growth rate as we support continued growth of operations.

Other income (expense), net

Other income (expense), net, primarily consists of interest income, offset by losses on extinguishment of debt, adjustments to fair value of acquisition liabilities, and losses on disposal of assets.

Interest expense

Interest expense is attributable to debt financing and capital leases. See Note 9 “Commitments and contingencies” in the Notes to Consolidated Financial Statements included elsewhere in this report.

Income tax benefit

Income tax benefit primarily consists of tax impacts of our deferred income tax asset assessments resulting from our acquisitions.

Critical accounting policies and estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

Revenue recognition

We generate test revenue primarily from delivery of test reports generated from our assays. Other revenue consists primarily of revenue from genome network subscription services which we recognize on a straight-line basis over the subscription term, and from revenue from collaboration agreements.

Effective January 1, 2018, we adopted ASC Topic 606. Under Topic 606 we generally recognize revenue on an accrual basis, that is when a customer obtains control of the promised goods or services which for us is delivery of a test report. Accrual amounts recognized under Topic 606 are based on an estimate of the consideration that we expect to receive, and such estimates will be adjusted and subsequently recorded until fully settled. The estimate of the consideration that we expect to receive requires significant judgment by management and any adjustments may be material. Prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for those periods.

Business Combinations - Purchase Accounting

We apply ASC 805, *Business Combinations*, or ASC 805, which is the accounting guidance related to business combinations. The standard requires recognition of assets acquired, liabilities assumed, and contingent consideration at their fair value on the acquisition date with subsequent changes recognized in earnings; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination and expensed as incurred; requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset until completion or abandonment; and requires that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of provision for taxes.

We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The purchase prices of acquisitions are allocated to tangible assets, liabilities and identifiable intangible assets acquired based on their estimated fair values. The excess of purchase prices over those fair values is recorded as goodwill. Acquisition-related expenses are expensed as incurred. While we use our best estimates and assumptions as a part of the process to accurately value assets acquired and liabilities assumed at the business combination date, these estimates and assumptions are inherently uncertain and subject to refinement. Our key assumptions used have included projected revenue, cost of goods sold and operating expenses for the acquired entities, as well as discount rates. As a result, during the measurement period, which may be up to one year from the business combination date, we may record adjustments to the assets acquired and liabilities assumed, with the corresponding offset to goodwill. After the measurement period, we record adjustments to assets acquired or liabilities assumed subsequent to the measurement period in our operating results in the period in which the adjustments were determined.

Goodwill

In accordance with ASC 350, *Intangibles - Goodwill and Other*, or ASC 350, we do not amortize goodwill or other intangible assets with indefinite lives but rather test them for impairment. ASC 350 requires us to perform an impairment review of our goodwill balance at least annually, which we do in the fourth quarter of each year for our single consolidated reporting unit, and whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable.

Stock-based compensation

Stock-based compensation expense is measured at the date of grant and is based on the estimated fair value of the award. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and restricted stock unit, or RSU, awards and on an accelerated basis for performance-based restricted stock unit, or PRSU, awards. We recognize stock-based compensation expense associated with PRSU grants when we determine the achievement of performance conditions is probable. In determining the fair value of stock options and Employee Stock Purchase Plan, or ESPP, purchases, we estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. We estimate the grant date fair value of RSU and PRSU awards based on the grant date share price.

We account for stock-based compensation arrangements with non-employees using a fair value approach. The fair value of these options is measured using the Black-Scholes option-pricing model reflecting the same assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option. The compensation expenses of these arrangements are subject to remeasurement over the vesting terms as earned.

For the years ended December 31, 2018, 2017 and 2016, we recorded stock-based compensation expense of \$20.9 million, \$19.2 million and \$10.7 million, respectively. At December 31, 2018, unrecognized compensation expense related to unvested stock options was \$4.5 million, which we expect to recognize over a weighted-average period of 1.8 years. Unrecognized compensation expense related to RSUs at December 31, 2018, net of estimated forfeitures, was \$22.6 million, which we expect to recognize on a straight-line basis over a weighted-average period of 2.1 years.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of stock-based awards. These assumptions include:

Expected term—The expected term represents the period that stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is based on the mid-point between the vesting date and the end of the contractual term.

Expected volatility—Because we were privately held until our initial public offering in February 2015 and did not have any trading history for our common stock, we have estimated expected volatility using our own stock price volatility when available as well as the average volatility for comparable publicly traded life sciences companies, including molecular diagnostics companies, over a period equal to the expected term of stock option grants and RSUs. When selecting comparable publicly-traded biopharmaceutical companies, including molecular diagnostics companies, we have selected companies with comparable characteristics to us, including enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected life of the stock-based awards. We have computed historical volatility data using daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own

stock price becomes available. We estimate expected volatility for ESPP purchases using our own stock price volatility over the expected six-month term of the ESPP purchase period.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of an option.

Dividend yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

	Year Ended December 31,		Dollar Change	% Change
	2018	2017		
Revenue:				
Test revenue	\$ 144,560	\$ 65,169	\$ 79,391	122%
Other revenue	3,139	3,052	87	3%
Total revenue	147,699	68,221	79,478	117%
Operating expenses:				
Cost of revenue	80,105	50,142	29,963	60%
Research and development	63,496	46,469	17,027	37%
Selling and marketing	74,428	53,417	21,011	39%
General and administrative	52,227	39,472	12,755	32%
Total operating expenses	270,256	189,500	80,756	43%
Loss from operations	(122,557)	(121,279)	(1,278)	1%
Other income (expense), net	(2,568)	(303)	(2,265)	748%
Interest expense	(7,030)	(3,654)	(3,376)	92%
Net loss before taxes	(132,155)	(125,236)	(6,919)	6%
Income tax benefit	(2,800)	(1,856)	(944)	51%
Net loss	\$ (129,355)	\$ (123,380)	\$ (5,975)	5%

Revenue

The increase in revenue of \$79.5 million for the year ended December 31, 2018 compared to the same period in 2017 was due primarily to increased test volume from growth in our historical business as well as the full year impact from our acquisitions of AltaVoice, Good Start Genetics and CombiMatrix completed in 2017. Billable test volumes increased to approximately 292,000 during the year ended December 31, 2018 compared to 145,000 in the same period in 2017. Average revenue per test increased to \$495 per test during the year ended December 31, 2018 compared to \$449 in the same period in 2017. Test revenue during the year ended December 31, 2018 included \$4.3 million of revenue recognized in 2018 relating to notification from Medicare of approval for payment of certain Current Procedure Terminology (CPT) codes and \$2.0 million in cash received from customers which exceeded our estimated collections.

Cost of revenue

The increase in the cost of revenue of \$30.0 million for the year ended December 31, 2018 compared to the same period in 2017 was primarily due to costs associated with increased test volume partially offset by the effect of cost efficiencies. For the year ended December 31, 2018, the number of samples accessioned increased to approximately 303,000 from approximately 150,000 for the same period in 2017. Cost per sample accessioned was \$264 in 2018 compared to \$335 in 2017. The decrease in the cost per sample accessioned was primarily attributable to increased volume which resulted in lower labor costs and to production improvements which resulted in material efficiencies, and to automation and software improvements which reduced the medical interpretation time per report.

Research and development

The increase in research and development expense of \$17.0 million for the year ended December 31, 2018 compared to the same period in 2017 was due to growth in the business and the effect of business acquisitions in 2017 and principally consisted of the following elements: personnel costs which increased by \$19.2 million due primarily to increases in headcount; lab expenses increased by \$4.8 million due to increases in development activities; depreciation and amortization expense increased by \$1.9 million principally due to amortization of intangible assets associated with business acquisitions; professional fees increased by \$1.5 million reflecting increased utilization of outside consultants; information technology costs increased by \$1.4 million due to increased spending on networking equipment and software licenses; and stock-based compensation costs increased by \$0.9 million and travel-related costs increased by \$0.6 million, both due to increases in headcount. These cost increases were partially offset by an increase of \$14.4 million in allocations of resources from research and development to cost of revenue, to support the increase in production volumes.

Selling and marketing

The increase in selling and marketing expenses of \$21.0 million for the year ended December 31, 2018 compared to the same period in 2017 was due to growth in the business and the effect of business acquisitions in 2017 and principally consisted of the following elements: increases in personnel costs of \$11.5 million due to increases in headcount, marketing costs, principally for branding initiatives, increased by \$3.2 million, travel expenses increased by \$2.3 million due to our growing sales force, amortization expense increased by \$1.5 million due to amortization of intangible assets associated with business acquisitions, stock-based compensation increased by \$0.9 million due to increases in headcount, and information technology costs increased by \$0.8 million.

General and administrative

The increase in general and administrative expenses of \$12.8 million for the year ended December 31, 2018 compared to the same period in 2017 was primarily due to the growth of the business and the effect of business acquisitions in 2017 and principally consisted of the following elements: personnel-related costs increased by \$6.5 million principally due to increases in headcount, including an internal billings and collections team hired to replace third-party billings and collection contractors; \$2.9 million of losses related to our collaboration agreement with KEW, Inc. with no similar expense in 2017; right of first refusal payments relating to the collaboration agreement with KEW and a separate co-development agreement with a different privately held genetics company were \$2.6 million with no similar costs in 2017 (see Note 8, "Investment in privately held company," and Note 9, "Commitments and contingencies," in the Notes to Consolidated Financial Statements included elsewhere in this report for further details on these arrangements); professional fees increased by \$2.3 million principally due to the utilization of outside consultants to augment existing staff; occupancy costs increased by \$2.2 million, due principally to costs related to facilities acquired through business acquisitions; information technology costs increased by \$1.5 million due primarily to computer equipment and software purchases to support headcount growth; and travel expenses increased by \$0.7 million due to increases in headcount.

These cost increases were offset by increased allocations of technology and facilities-related expenses to other functional areas of \$2.9 million, reduction of depreciation and amortization costs of \$1.5 million and a decrease in stock-based compensation of \$1.0 million.

Other income (expense), net

The increase in other expense, net of \$2.3 million for the year ended December 31, 2018 compared to the same period in 2017 was principally due to a loss on extinguishment of debt of \$5.3 million recorded in November 2018 compared to \$0.7 million in 2017. This charge in November 2018 related to our repayment in full, and prior to the scheduled maturity date, of the balance of our obligations under a Loan and Security Agreement entered into in 2017 ("2017 Loan Agreement"). This was partially offset by a gain on remeasurement of an acquisition-related liability from AltaVoice of \$1.6 million in the first quarter of 2018 as well as an increase in interest income of \$0.7 million.

Interest expense

The increase in interest expense of \$3.4 million for the year ended December 31, 2018 compared to the same period in 2017 was due principally to the impact of borrowings under the 2017 Loan Agreement entered into in March 2017 as well as borrowings under a separate arrangement in November 2018. See Note 9, "Commitments and contingencies" in the Notes to Consolidated Financial Statements included elsewhere in this report.

Income tax benefit

The increase in income tax benefit of \$0.9 million for the year ended December 31, 2018 compared to the same period in 2017 was due primarily to changes in our deferred income taxes during 2017 resulting from the completion of our analyses associated with the acquisitions of AltaVoice and Ommdom as compared to changes in our deferred income taxes during 2018 resulting from the completion of our analysis of historical net operating losses for CombiMatrix.

Comparison of the Years Ended December 31, 2017 and 2016

	Year Ended December 31,		Dollar Change	%
	2017	2016		
Revenue:				
Test revenue	\$ 65,169	\$ 24,840	\$ 40,329	162 %
Other revenue	3,052	208	2,844	1,367 %
Total revenue	68,221	25,048	43,173	172 %
Operating expenses:				
Cost of revenue	50,142	27,878	22,264	80 %
Research and development	46,469	44,630	1,839	4 %
Selling and marketing	53,417	28,638	24,779	87 %
General and administrative	39,472	24,085	15,387	64 %
Total operating expenses	189,500	125,231	64,269	51 %
Loss from operations	(121,279)	(100,183)	(21,096)	21 %
Other income (expense), net	(303)	348	(651)	(187)%
Interest expense	(3,654)	(421)	(3,233)	768 %
Net loss before taxes	(125,236)	(100,256)	(24,980)	25 %
Income tax benefit	(1,856)	—	(1,856)	(100)%
Net loss	\$ (123,380)	\$ (100,256)	\$ (23,124)	23 %

Revenue

The increase in total revenue of \$43.2 million for the year ended December 31, 2017 compared to the same period in 2016 was due primarily to increased test volume from our historical business and test and other revenues from our acquisitions of AltaVoice, Good Start Genetics and CombiMatrix. Revenue recognized on a cash basis was \$46.4 million in the year ended December 31, 2017 compared to \$21.3 million in the same period in 2016, and this increase was principally attributable to increased test volumes from our historical business. Revenue recognized on an accrual basis was \$21.8 million in the year ended December 31, 2017 compared to \$3.6 million in the same period in 2016. Of this increase, \$7.2 million was attributable to increased test volumes from our historical business, \$6.2 million was attributable to revenues relating to our acquisition of Good Start Genetics, \$2.8 million was attributable to genome network revenues relating to our acquisition of AltaVoice and \$2.0 million was attributable to revenues relating to our acquisition of CombiMatrix.

Cost of revenue

The increase in the cost of revenue of \$22.3 million for the year ended December 31, 2017 compared to the same period in 2016 was primarily due to costs associated with increased test volume partially offset by the effect of cost efficiencies. For the year ended December 31, 2017, the number of samples accessioned increased to approximately 150,000 from approximately 59,000 for the same period in 2016. This increase included approximately 13,000 Good Start Genetics samples and 2,000 CombiMatrix samples. Cost per sample accessioned was \$335 in 2017 compared to \$473 in 2016. The decrease in the cost per sample was primarily attributable to increased volume, which led to higher labor efficiencies, to production improvements which resulted in lower materials costs, and to automation and software improvements which have reduced the medical interpretation time per report.

Research and development

The increase in research and development expense of \$1.8 million for the year ended December 31, 2017 compared to the same period in 2016 was due primarily to personnel costs which increased by \$3.3 million principally reflecting the acquisitions of Good Start Genetics and CombiMatrix. Facilities and information technology costs increased by \$2.8 million reflecting costs associated with our new production facility and headquarters, which became fully operational in February 2017. Stock-based compensation costs increased by \$1.2 million and depreciation expense increased by \$0.7 million. These cost increases were partially offset by an increase of \$6.5 million in allocations of resources from research and development to cost of revenue, reflecting increased test volumes.

Selling and marketing

The increase in selling and marketing expenses of \$24.8 million for the year ended December 31, 2017 compared to the same period in 2016 was due primarily to increased personnel costs of \$16.1 million including increases of \$12.4 million in salaries and benefits, \$2.8 million in sales commissions and \$0.9 million in other payroll related costs. Facilities and information technology costs increased by \$4.7 million, reflecting costs associated with our new production facility and headquarters, which became fully operational in February 2017. Stock-based compensation increased by \$2.2 million and travel costs increased by \$2.1 million reflecting our growing sales force. In addition, marketing costs increased by \$1.0 million and professional services costs increased by \$0.4 million.

These cost increases were partially offset by an increase of \$1.9 million in allocations of resources from sales and marketing to cost of revenue, reflecting increased test volumes and sign-out activity. In addition, depreciation and amortization costs decreased by \$0.2 million.

General and administrative

The increase in general and administrative expenses of \$15.4 million for the year ended December 31, 2017 compared to the same period in 2016 was primarily due to increased personnel costs of \$5.7 million. Headcount increased principally due to hiring an internal billings and collection team to replace third-party billings and collections contractors. Headcount also increased due to the acquisitions of Good Start Genetics and CombiMatrix. Stock-based compensation increased by \$4.4 million due principally to acquisition-related stock compensation expense for Good Start Genetics and CombiMatrix. Depreciation and amortization expense increased by \$2.3 million, due primarily to intangible asset amortization of \$1.6 million in 2017 and increased depreciation expense of \$0.7 million principally for leasehold improvements associated with our new production facility and headquarters. Occupancy costs increased by \$2.1 million, principally reflecting costs associated with our new production facility and headquarters. Acquisition-related legal and accounting fees increased by \$1.8 million, internal billing and collection costs increased by \$1.5 million and legal costs increased by \$1.2 million. Professional fees increased by \$1.4 million, principally due to third-party billings and collection costs reflecting increased sales volumes and costs related to running dual billing systems for a portion of 2017 as we moved from a third-party billing agency to in-house billing. Information technology costs increased by \$1.1 million due principally to computer equipment and software purchases to support headcount growth.

These cost increases were offset by increased allocations of technology and facilities-related expenses to other functional areas of \$7.5 million, reflecting the allocation of costs associated with our new production facility and headquarters, which became fully operational in February 2017. From February 2016 to January 2017, we recorded rent expense for our new production facility and headquarters as general and administrative expense. Beginning in February 2017, we began allocating this cost across our organization.

Other income (expense), net

The decrease in other income (expense), net of \$0.7 million for the year ended December 31, 2017 compared to the same period in 2016 was principally due to a loss on extinguishment of debt of \$0.7 million recorded in March 2017. This charge related to our repayment in full, and prior to the scheduled maturity date, of the balance of our obligations under an agreement entered into in July 2015, or the 2015 Loan Agreement.

Interest expense

The increase in interest expense of \$3.2 million for the year ended December 31, 2017 compared to the same period in 2016 was due principally to borrowings, under the 2017 Loan Agreement. See Note 9, "Commitments and contingencies" in the Notes to Consolidated Financial Statements included elsewhere in this report. We borrowed \$40.0 million pursuant to the 2017 Loan Agreement in March 2017.

Income tax benefit

The income tax benefit of \$1.9 million recorded in the year ended December 31, 2017 was due to changes in our deferred income tax asset valuation allowances resulting from our acquisitions of AltaVoice in January 2017 and Ommdom in June 2017.

Liquidity and capital resources

Liquidity and capital expenditures

We have incurred net losses since our inception. For the years ended December 31, 2018, 2017 and 2016, our net losses were \$129.4 million, \$123.4 million and \$100.3 million, respectively, and we expect to incur additional losses in the near term. At December 31, 2018, we had an accumulated deficit of \$516.7 million. While our revenue has increased over time, we may never achieve revenue sufficient to offset our expenses.

Since inception, our operations have been financed primarily by net proceeds from sales of our capital stock, fees collected from our customers as well as borrowing from debt facilities.

From inception through December 31, 2018, we have entered into various capital lease agreements for an aggregate financing amount of \$15.2 million to obtain laboratory equipment. The terms of our capital leases are typically three years and are secured by the underlying equipment.

In November 2018, we entered into a Note Purchase Agreement (the "2018 Note Purchase Agreement") pursuant to which we are eligible to borrow an aggregate principal amount up to \$200.0 million over its maturity term of 7 years which includes an initial borrowing of \$75.0 million in November 2018 which we used to extinguish our previous debt. The outstanding principal amount under the 2018 Note Purchase Agreement bears interest at a rate of 8.75% annually. In addition, beginning on January 1, 2020 and continuing until the maturity date, we will make quarterly payments of 0.5% of our annual net revenues subject to a maximum annual amount of such payments of \$1.6 million which will be recognized as interest expense. Through the fixed interest charges and the quarterly revenue payments, we are required to pay total amounts to generate an 11% internal rate of return to the lender on any outstanding principal balances due in a lump-sum upon the repayment or maturity of any outstanding principal. See more details on the 2018 Note Purchase Agreement in Note 9, "Commitments and contingencies" in the Notes to Consolidated Financial Statements included elsewhere in this report.

The 2018 Note Purchase Agreement contains quarterly covenants to achieve certain revenue levels as well as additional covenants, including limits on our ability to dispose of assets, undergo a change of control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions.

In connection with the 2018 Note Purchase Agreement, in November 2018, we entered into a Securities Purchase Agreement pursuant to which the lender purchased 373,524 shares of our common stock at a price of \$13.39 per share for an aggregate amount of \$5.0 million. The price paid by the lender was calculated based on the 15-day average closing share price prior to the issuance. The fair value of the common stock purchased by the lender was \$5.4 million.

At December 31, 2018 and 2017, we had \$131.9 million and \$76.0 million, respectively, of cash, cash equivalents, restricted cash and marketable securities.

Our primary uses of cash are to fund our operations as we continue to grow our business and potentially to acquire businesses and technologies. Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We estimate our capital expenditures for the full year 2019 will be approximately \$10.0 million.

We have incurred substantial losses since our inception, and we expect to continue to incur losses in the near term. We believe our existing cash, cash equivalents and marketable securities as of December 31, 2018, revenue from the sale of our tests, and notes available to us pursuant to the 2018 Note Purchase Agreement, will be sufficient to meet our anticipated cash requirements for the foreseeable future.

We may need additional funding to finance operations prior to achieving profitability or should we make additional acquisitions. We regularly consider fundraising opportunities and will determine the timing, nature and size of future financings based upon various factors, including market conditions and our operating plans. We may in the future elect to finance operations by selling equity or debt securities or borrowing money. We also may elect to finance future acquisitions. If we issue equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. In addition, the terms of debt securities or borrowings could impose significant restrictions on our operations. If additional funding is required, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all. If we are unable to obtain additional funding when needed, we will need to curtail planned activities to reduce costs. Doing so will likely have an unfavorable effect on our ability to execute on our business plan, and have an adverse effect on our business, results of operations and future prospects.

The following table summarizes our cash flows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cash used in operating activities	\$ (92,220)	\$ (97,981)	\$ (76,317)
Cash provided by (used in) investing activities	35,773	(36,953)	16,061
Cash provided by financing activities	157,152	80,871	53,709
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 100,705</u>	<u>\$ (54,063)</u>	<u>\$ (6,547)</u>

Cash flows from operating activities

For the year ended December 31, 2018, cash used in operating activities of \$92.2 million principally resulted from our net loss of \$129.4 million offset by non-cash charges of \$20.9 million for stock-based compensation, \$13.5 million for depreciation and amortization, \$5.3 million related to debt extinguishment costs, \$2.9 million of impairment losses related to our collaboration agreement with KEW, \$0.8 million of other non-cash adjustments and \$0.4 million for remeasurements of liabilities associated with business combinations, all partially offset by a \$2.9 million benefit from income taxes resulting from the completion of our analysis of historical net operating losses for CombiMatrix. The net effect on cash of changes in net operating assets was a use of cash of \$3.8 million due principally to the effect of increase in accounts receivable due to timing of collections partially offset by an increase in accrued and other liabilities.

For the year ended December 31, 2017, cash used in operating activities of \$98.0 million principally resulted from our net loss of \$123.4 million and non-cash income tax benefits offset by non-cash charges of \$19.2 million for stock-based compensation, \$9.2 million for depreciation and amortization and \$1.8 million for remeasurements of liabilities associated with business combinations. The net effect on cash of changes in net operating assets was a use of cash of \$3.4 million due principally to the effect of increase in accounts receivable.

For the year ended December 31, 2016, cash used in operating activities of \$76.3 million principally resulted from our net loss of \$100.3 million offset by non-cash charges of \$10.7 million for stock-based compensation, \$6.6 million for depreciation and amortization and \$1.0 million for asset impairment charges. The net effect on cash of changes in net operating assets was \$5.3 million and was due principally to the effect of increases in accrued expenses and other assets.

Cash flows from investing activities

For the year ended December 31, 2018, cash provided by investing activities of \$35.8 million resulted primarily from proceeds from maturities and sales of marketable securities exceeding purchases of marketable securities by \$42.7 million and purchases of property and equipment of \$6.0 million.

For the year ended December 31, 2017, cash used in investing activities of \$37.0 million resulted primarily from purchases of marketable securities exceeding proceeds from maturities of marketable securities by \$33.1 million and purchases of property and equipment of \$6.7 million, partially offset by \$2.8 million cash acquired from acquisition of businesses.

For the year ended December 31, 2016, cash provided by investing activities of \$16.1 million resulted primarily from proceeds from maturities of marketable securities exceeding purchases of marketable securities by \$27.7 million, partially offset by purchases of property and equipment of \$11.6 million.

Cash flows from financing activities

For the year ended December 31, 2018, cash provided by financing activities of \$157.2 million consisted of net proceeds from the public offerings of common stock of \$112.4 million, net proceeds of \$93.9 million from the second term loan under the Amended 2017 Loan Agreement and from the 2018 Note Purchase Agreement, and cash received from issuances of common stock totaling \$17.5 million (which includes \$6.5 million received from exercises of warrants issued pursuant to the acquisition of CombiMatrix (see Note 4, "Business combinations," in the Notes to Consolidated Financial Statements included elsewhere in this report), \$5.0 million received pursuant to the Securities Purchase Agreement entered into in connection with our 2018 Note Purchase Agreement, employee stock purchases of \$3.2 million, and stock option exercises of \$2.7 million). These cash inflows were partially offset by loan payments of \$60.0 million to extinguish our 2017 Loan Agreement, payments of \$4.6 million related to the extinguishment of our 2017 Loan Agreement and related amendments and capital lease payments of \$2.1 million.

For the year ended December 31, 2017, cash provided by financing activities of \$80.9 million consisted of net proceeds of \$68.9 million from a private placement, net proceeds of \$39.7 million from an initial term loan under the 2017 Loan Agreement and cash received from employee stock plan purchases, exercises of stock options and exercises of warrants totaling \$5.7 million. These cash inflows were partially offset by a cash payment of \$18.4 million to settle loan obligations assumed in the Good Start acquisition, other loan payments of \$12.1 million and capital lease obligations payments of \$3.0 million.

For the year ended December 31, 2016, cash provided by financing activities of \$53.7 million resulted from net proceeds from an underwritten public offering of common stock of \$47.1 million, borrowings of \$7.5 million under the a loan agreement and cash received from exercises of stock options of \$3.1 million, partially offset by loan payments of \$2.4 million and capital lease obligations payments of \$1.6 million.

Contractual obligations

The following table summarizes our contractual obligations, including interest, as of December 31, 2018 (in thousands):

Contractual obligations:	2019	2020 and 2021	2022 and 2023	2024 and beyond	Total
Operating leases ⁽¹⁾	\$ 10,774	\$ 21,969	\$ 19,965	\$ 25,715	\$ 78,423
Capital leases	2,087	1,413	—	—	3,500
Debt	6,654	16,576	16,558	89,998	129,786
Purchase commitments	3,040	4,480	—	—	7,520
Total	\$ 22,555	\$ 44,438	\$ 36,523	\$ 115,713	\$ 219,229

⁽¹⁾ Operating lease commitments are net of total sublease payments of \$0.2 million.

In September 2015, we entered into a lease agreement for our current production facility and headquarters in San Francisco, California, in which we commenced occupancy and operations in January 2017. This lease expires in July 2026. Leases for other facilities in California and Massachusetts expire at various dates from 2019 through 2026. Aggregate future minimum lease payments for these facilities are included in the table above.

Debt in the table above includes principal and interest payments pertaining our 2018 Note Purchase Agreement.

In the normal course of business, we enter into various purchase commitments primarily related to service agreements, laboratory supplies and a co-development agreement. Our total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year are included above.

See Note 9, "Commitments and contingencies" in the Notes to Consolidated Financial Statements for additional details regarding our leases, debt, and purchase commitments.

Off-balance sheet arrangements

We have not entered into any off-balance sheet arrangements. See Note 8, "Investments in privately held company" in the Notes to Consolidated Financial Statements included elsewhere in this report for a discussion of our holding in a variable interest entity.

Recent accounting pronouncements

See “Recent accounting pronouncements” in Note 2, “Summary of significant accounting policies” in the Notes to Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and accounting pronouncements not yet adopted, and their expected effect on our financial position and results of operations.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had loan obligations under our 2018 Note Purchase Agreement of \$74.5 million at December 31, 2018. This loan is subject to a fixed interest rate, plus beginning on January 1, 2020 and continuing until the maturity date, quarterly payments of 0.5% of our annual net revenues subject to a maximum annual amount of such payments of \$1.6 million. We had capital lease obligations of \$3.3 million as of December 31, 2018, which result from various capital lease agreements to obtain laboratory equipment. Our capital lease obligations carry fixed rates of interest. Our cash, cash equivalents, restricted cash and marketable securities totaled \$131.9 million at December 31, 2018, and consisted of bank deposits, commercial paper, money market funds, U.S. treasury notes, and U.S. government agency securities. Such interest-bearing instruments carry a degree of risk; however, because our investments are primarily short-term in duration, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. At December 31, 2018, a hypothetical 1% (100 basis points) increase or decrease in interest rates would not have resulted in a material change in the fair value of our cash equivalents and portfolio of marketable securities. Fluctuations in the value of our cash equivalents and portfolio of marketable securities caused by a change in interest rates (gains or losses on the carrying value) are recorded in other comprehensive gain (loss) and are realized only if we sell the underlying securities prior to maturity or declines in fair value are determined to be other-than-temporary.

ITEM 8. Consolidated Financial Statements and Supplementary Data.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Invitae Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Invitae Corporation (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Adoption of ASU No. 2014-09

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for revenue in 2018 due to the adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), and the related amendments.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.

Redwood City, California
February 28, 2019

INVITAE CORPORATION

Consolidated Balance Sheets
(in thousands, except par value data)

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 112,158	\$ 12,053
Marketable securities	13,727	52,607
Accounts receivable	26,296	10,422
Prepaid expenses and other current assets	13,258	11,599
Total current assets	<u>165,439</u>	<u>86,681</u>
Property and equipment, net	27,886	30,341
Restricted cash	6,006	5,406
Marketable securities, non-current	—	5,983
Intangible assets, net	30,469	35,516
Goodwill	50,095	46,575
Other assets	3,064	576
Total assets	<u>\$ 282,959</u>	<u>\$ 211,078</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 7,812	\$ 8,606
Accrued liabilities	26,563	22,742
Capital lease obligation, current portion	1,937	2,039
Total current liabilities	<u>36,312</u>	<u>33,387</u>
Capital lease obligation, net of current portion	1,375	3,373
Debt	74,477	39,084
Other long-term liabilities	8,956	13,440
Total liabilities	<u>121,120</u>	<u>89,284</u>
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value: 20,000 shares authorized; 3,459 shares issued and outstanding as of December 31, 2018 and 2017	—	—
Common stock, \$0.0001 par value: 400,000 shares authorized; 75,481 and 53,597 shares issued and outstanding as of December 31, 2018 and 2017, respectively	8	5
Accumulated other comprehensive loss	(5)	(171)
Additional paid-in capital	678,548	520,558
Accumulated deficit	(516,712)	(398,598)
Total stockholders' equity	<u>161,839</u>	<u>121,794</u>
Total liabilities and stockholders' equity	<u>\$ 282,959</u>	<u>\$ 211,078</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Operations
(in thousands, except per share data)

	Year Ended December 31,		
	2018	2017	2016
Revenue:			
Test revenue	\$ 144,560	\$ 65,169	\$ 24,840
Other revenue	3,139	3,052	208
Total revenue	<u>147,699</u>	<u>68,221</u>	<u>25,048</u>
Costs and operating expenses:			
Cost of revenue	80,105	50,142	27,878
Research and development	63,496	46,469	44,630
Selling and marketing	74,428	53,417	28,638
General and administrative	52,227	39,472	24,085
Total costs and operating expenses	<u>270,256</u>	<u>189,500</u>	<u>125,231</u>
Loss from operations	(122,557)	(121,279)	(100,183)
Other income (expense), net	(2,568)	(303)	348
Interest expense	(7,030)	(3,654)	(421)
Net loss before taxes	(132,155)	(125,236)	(100,256)
Income tax benefit	(2,800)	(1,856)	—
Net loss	<u>\$ (129,355)</u>	<u>\$ (123,380)</u>	<u>\$ (100,256)</u>
Net loss per share, basic and diluted	<u>\$ (1.94)</u>	<u>\$ (2.65)</u>	<u>\$ (3.02)</u>
Shares used in computing net loss per share, basic and diluted	<u>66,747</u>	<u>46,512</u>	<u>33,176</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	\$ (129,355)	\$ (123,380)	\$ (100,256)
Other comprehensive income (loss):			
Unrealized income (loss) on available-for-sale marketable securities, net of tax	166	(171)	15
Comprehensive loss	<u>\$ (129,189)</u>	<u>\$ (123,551)</u>	<u>\$ (100,241)</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity
(in thousands)

	Convertible		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Preferred Stock		Shares	Amount				
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2015	—	\$ —	31,935	\$ 4	\$ 313,349	\$ (15)	\$ (174,962)	\$ 138,376
Common stock issued on exercise of stock options	—	—	244	—	744	—	—	744
Common stock issued pursuant to vesting of restricted stock units	—	—	157	(1)	—	—	—	(1)
Common stock issued pursuant to employee stock purchase plan	—	—	370	—	2,391	—	—	2,391
Common stock issued in connection with underwritten public offering, net of offering costs of \$3,498	—	—	8,433	1	47,101	—	—	47,102
Vesting of common stock related to early exercise of options	—	—	5	—	4	—	—	4
Stock-based compensation expense	—	—	—	—	10,699	—	—	10,699
Unrealized income (loss) on available-for-sale marketable securities, net of tax	—	—	—	—	—	15	—	15
Net loss	—	—	—	—	—	—	(100,256)	(100,256)
Balance as of December 31, 2016	—	—	41,144	4	374,288	—	(275,218)	99,074
Common and convertible preferred stock issued in private placement, net of offering costs of \$4,599	3,459	—	5,188	1	68,896	—	—	68,897
Common stock issued on exercise of stock options, net	—	—	387	—	1,706	—	—	1,706
Common stock issued pursuant to vesting of restricted stock units, net	—	—	925	—	—	—	—	—
Common stock issued pursuant to acquisition-related transaction bonus	—	—	4	—	—	—	—	—
Common stock issued pursuant to exercises of warrants	—	—	232	—	1,381	—	—	1,381
Common stock issued pursuant to employee stock purchase plan	—	—	379	—	2,635	—	—	2,635
Common stock issued pursuant to business combinations	—	—	5,176	—	50,808	—	—	50,808
Common stock issued to settle assumed liabilities	—	—	162	—	1,272	—	—	1,272
Warrants issued pursuant to the 2017 Loan Agreement	—	—	—	—	740	—	—	740
Stock-based compensation expense	—	—	—	—	18,832	—	—	18,832
Unrealized income (loss) on available-for-sale marketable securities, net of tax	—	—	—	—	—	(171)	—	(171)
Net loss	—	—	—	—	—	—	(123,380)	(123,380)
Balance as of December 31, 2017	3,459	—	53,597	5	520,558	(171)	(398,598)	121,794
Cumulative effect of accounting change	—	—	—	—	—	—	11,241	11,241
Common stock issued in connection with public offering, net of offering costs of \$6,183	—	—	17,103	3	112,438	—	—	112,441
Common stock issued on exercise of stock options, net	—	—	351	—	2,741	—	—	2,741
Common stock issued pursuant to vesting of restricted stock units, net	—	—	1,369	—	—	—	—	—
Common stock issued pursuant to exercises of warrants	—	—	1,099	—	6,539	—	—	6,539
Common stock issued pursuant to employee stock purchase plan	—	—	566	—	3,231	—	—	3,231
Common stock issued pursuant to business combinations	—	—	1,022	—	6,455	—	—	6,455
Warrants issued pursuant to 2017 Loan Agreement	—	—	—	—	383	—	—	383
Common stock issued pursuant to Securities Purchase Agreement (see Note 9)	—	—	374	—	5,353	—	—	5,353
Stock-based compensation expense	—	—	—	—	20,850	—	—	20,850
Unrealized income (loss) on available-for-sale marketable securities, net of tax	—	—	—	—	—	166	—	166
Net loss	—	—	—	—	—	—	(129,355)	(129,355)
Balance as of December 31, 2018	3,459	\$ —	75,481	\$ 8	\$ 678,548	\$ (5)	\$ (516,712)	\$ 161,839

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	\$ (129,355)	\$ (123,380)	\$ (100,256)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	13,540	9,181	6,553
Stock-based compensation	20,850	19,221	10,699
Impairment losses	2,925	—	—
Remeasurements of liabilities associated with business combinations	362	1,810	—
Benefit from income taxes	(2,862)	(1,856)	—
Debt extinguishment costs	5,266	—	—
Other	806	404	1,341
Changes in operating assets and liabilities, net of effects of business combination:			
Accounts receivable	(5,291)	(1,963)	(843)
Prepaid expenses and other current assets	(1,445)	(641)	(1,149)
Other assets	(163)	(185)	1,465
Accounts payable	(417)	(535)	(111)
Accrued expenses and other liabilities	3,564	(37)	5,984
Net cash used in operating activities	<u>(92,220)</u>	<u>(97,981)</u>	<u>(76,317)</u>
Cash flows from investing activities:			
Purchases of marketable securities	(9,680)	(101,867)	(90,236)
Proceeds from sales of marketable securities	19,965	—	—
Proceeds from maturities of marketable securities	32,458	68,768	117,922
Acquisition of businesses, acquired cash	—	2,821	—
Purchases of property and equipment	(5,970)	(6,675)	(11,625)
Other	(1,000)	—	—
Net cash provided by (used in) investing activities	<u>35,773</u>	<u>(36,953)</u>	<u>16,061</u>
Cash flows from financing activities:			
Proceeds from public offering of common stock, net of issuance costs	112,441	—	47,102
Proceeds from issuance of common stock	17,511	74,619	3,134
Net proceeds from issuance of debt	93,909	39,661	7,500
Payments for debt extinguishment costs	(4,609)	—	—
Loan payments	(60,000)	(30,457)	(2,438)
Capital lease principal payments	(2,100)	(2,952)	(1,589)
Net cash provided by financing activities	<u>157,152</u>	<u>80,871</u>	<u>53,709</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	100,705	(54,063)	(6,547)
Cash, cash equivalents and restricted cash at beginning of period	17,459	71,522	78,069
Cash, cash equivalents and restricted cash at end of period	<u>\$ 118,164</u>	<u>\$ 17,459</u>	<u>\$ 71,522</u>
Supplemental cash flow information:			
Interest paid	\$ 6,231	\$ 2,852	\$ 421

Equipment acquired through capital leases	\$ —	\$ 6,789	\$ —
Purchases of property and equipment in accounts payable and accrued liabilities	\$ 510	\$ 200	\$ 1,644
Amounts related to co-development agreement in other assets and accrued liabilities	\$ 2,000	\$ —	\$ —
Warrants issued pursuant to 2017 Loan Agreement	\$ 383	\$ 740	\$ —
Common stock issued for acquisition of businesses	\$ 6,445	\$ 50,808	\$ —
Consideration payable for acquisition of businesses	\$ —	\$ 13,276	\$ —
Common stock issued to settle assumed liabilities	\$ —	\$ 1,272	\$ —

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Notes to Consolidated Financial Statements

1. Organization and description of business

Invitae Corporation (the “Company”) was incorporated in the State of Delaware on January 13, 2010, as Locus Development, Inc. and changed its name to Invitae Corporation in 2012. The Company utilizes an integrated portfolio of laboratory processes, software tools and informatics capabilities to process DNA-containing samples, analyze information about patient-specific genetic variation and generate test reports for clinicians and their patients. The Company’s headquarters and main production facility is located in San Francisco, California. The Company currently has more than 20,000 genes in production and provides a variety of diagnostic tests that can be used in multiple indications. The Company’s tests include genes associated with hereditary cancer, neurological disorders, cardiovascular disorders, pediatric disorders, metabolic disorders and other hereditary conditions. In addition, and as a result of the acquisitions of Good Start Genetics (“Good Start”) in August 2017 and CombiMatrix Corporation (“CombiMatrix”) in November 2017, the Company’s services also include screening and testing in reproductive health, including preimplantation and carrier screening for inherited disorders, prenatal diagnosis, miscarriage analysis and pediatric developmental disorders. The Company operates in one segment.

2. Summary of significant accounting policies

Principles of consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. The Company bases these estimates on historical and anticipated results, trends and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. Actual results could differ materially from those estimates and assumptions.

Significant estimates and assumptions made by management include the determination of:

- revenue recognition (See Note 3, “Revenue, accounts receivable and deferred revenue” for further information);
- the fair value of assets acquired and liabilities assumed for business combinations;
- the fair value of goodwill and intangible assets;
- the recoverability of long-lived assets;
- stock-based compensation expense and the fair value of awards issued; and
- income tax uncertainties.

Concentrations of credit risk and other risks and uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents, marketable securities and accounts receivable. The Company’s cash and cash equivalents are held by financial institutions in the United States. Such deposits may exceed federally insured limits.

Significant customers are those that represent 10% or more of the Company’s total revenue for each year presented on the statements of operations. For the significant customer, revenue as a percentage of total revenue were as follows:

Customers	December 31,		
	2018	2017	2016
Medicare	22%	13%	11%

Medicare represented 21% and 13% of accounts receivable as of December 31, 2018 and 2017.

Cash, cash equivalents, and restricted cash

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds and U.S. government agency securities.

Restricted cash consists of money market funds that serve as collateral for security deposits for the Company's facility lease and sublease agreements and collateral for a credit card agreement at one of the Company's financial institutions.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the statements of cash flows (in thousands):

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Cash and cash equivalents	\$ 112,158	\$ 12,053
Restricted cash	6,006	5,406
Total cash, cash equivalents and restricted cash	<u>\$ 118,164</u>	<u>\$ 17,459</u>

Marketable securities

All marketable securities have been classified as "available-for-sale" and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its marketable debt securities at the time of purchase and reevaluates such designation at each balance sheet date. Short-term marketable securities have maturities less than 365 days at the balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in interest and other income (expense), net. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in interest and other income (expense), net.

Accounts receivable

The Company receives payment for its tests from partners, patients, institutional customers and third-party payers. See Note 3, "Revenue, accounts receivable and deferred revenue" for further information.

Inventory

The Company maintains test reagents and other consumables primarily used in sample collection kits which are valued at the lower of cost or market value. Cost is determined using actual costs on a first-in, first-out basis. The Company's inventory was \$8.3 million and \$5.4 million as of December 31, 2018 and 2017, respectively, and was recorded in prepaid expenses and other current assets in the Company's consolidated balance sheets.

Business combinations

The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. The Company bases the estimated fair value of identifiable intangible assets acquired in a business combination on independent valuations that use information and assumptions provided by management, which consider management's estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 480, *Distinguishing Liabilities from Equity*, the Company recognizes a liability equal to the fair value of the contingent payments the Company expects to make as of the acquisition date. The Company remeasures this liability each reporting period and records changes in the fair value as a component of operating expenses.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in the Company's operating results from the date of acquisition.

Intangible assets

Amortizable intangible assets include trade names, non-compete agreements, developed technology and customer relationships acquired as part of business combinations. Customer relationships are amortized on an accelerated basis, utilizing free cash flows, over periods ranging from five to 11 years. All other intangible assets subject to amortization are amortized using the straight-line method over their estimated useful lives ranging from two to 15 years. All intangible assets subject to amortization are reviewed for impairment in accordance with ASC 360, *Property, Plant and Equipment*.

Goodwill

In accordance with ASC 350, *Intangibles-Goodwill and Other* ("ASC 350"), the Company's goodwill is not amortized but is tested for impairment on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. Under ASC 350, the Company performs annual impairment reviews of its goodwill balance during the fourth fiscal quarter. In testing for impairment, the Company compares the fair value of its reporting unit to its carrying value including the goodwill of that unit. If the carrying value, including goodwill, exceeds the reporting unit's fair value, the Company will recognize an impairment loss for the amount by which the carrying amount exceeds the reporting unit's fair value. The loss recognized cannot exceed the total amount of goodwill allocated to that reporting unit. The Company did not incur any goodwill impairment losses in any of the periods presented.

Leases

The Company rents its facilities under operating lease agreements and recognizes related rent expense on a straight-line basis over the term of the applicable lease agreement. Some of the lease agreements contain rent holidays, scheduled rent increases, lease incentives, and renewal options. Rent holidays and scheduled rent increases are included in the determination of rent expense to be recorded over the lease term. Lease incentives are recognized as a reduction of rent expense on a straight-line basis over the term of the lease. Renewals are not assumed in the determination of the lease term unless they are deemed to be reasonably assured at the inception of the lease. The Company recognizes rent expense beginning on the date it obtains the legal right to use and control the leased space.

Property and equipment, net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and seven years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease. Amortization expense of assets acquired through capital leases is included in depreciation and amortization expense in the consolidated statements of operations. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the statements of operations in the period realized.

The estimated useful lives of property and equipment are as follows:

Furniture and fixtures	7 years
Automobiles	7 years
Laboratory equipment	5 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	Shorter of lease term or estimated useful life

Long-lived assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows or other appropriate measures of fair value. Other than impairment losses of \$1.0 million in 2016 relating to leasehold improvements and to the shutdown of the Company’s Chilean operations, there were no long-lived asset impairment losses recorded for any period presented. All impairment losses were charged to general and administrative expense.

Variable interest entity

The Company had a variable interest in a variable interest entity (“VIE”) through an investment in convertible notes issued by the VIE. The convertible notes do not provide the Company with voting rights in the VIE or with power to direct the activities of the VIE which most significantly affect its economic performance. The Company is not the VIE’s primary beneficiary and it does not consolidate the VIE.

Fair value of financial instruments

The Company’s financial instruments consist principally of cash and cash equivalents, marketable securities, accounts payable, accrued liabilities, capital leases and debt. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued and other current liabilities approximate their current fair value due to the relatively short-term nature of these accounts. Based on borrowing rates available to the Company, the carrying value of capital leases and debt approximate their fair values.

Revenue recognition

The Company recognizes revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration it expects to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers.

Test revenue is generated primarily from the sale of tests that provide analysis and associated interpretation of the sequencing of parts of the genome.

Other revenue consists primarily of revenue from genome network subscription services which is recognized on a straight-line basis over the subscription term, and revenue from collaboration agreements.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering the genetic testing results to clinicians and includes expenses for personnel-related costs including stock-based compensation, materials and supplies, equipment and infrastructure expenses associated with testing and allocated overhead including rent, equipment depreciation and utilities.

Income taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

Stock-based compensation

The Company measures its stock-based payment awards made to employees and directors based on the estimated fair values of the awards and recognizes the compensation expense over the requisite service period. The Company uses the Black-Scholes option-pricing model to estimate the fair value of its stock option awards and employee stock purchase plan ("ESPP") purchases. The fair value of restricted stock unit ("RSU") awards with time-based vesting terms is based on the grant date share price. The Company grants performance-based restricted stock unit ("PRSU") awards to certain employees which vest upon the achievement of certain performance conditions, subject to the employees' continued service relationship with the Company. The probability of vesting is assessed at each reporting period and compensation cost is adjusted based on this probability assessment. The Company recognizes such compensation expense on an accelerated vesting method.

Stock-based compensation expense for awards without a performance condition is recognized using the straight-line method. Stock-based compensation expense is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, the Company's stock-based compensation is reduced for estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company accounts for compensation expense related to stock options granted to non-employees based on fair values estimated using the Black-Scholes option-pricing model. Stock options granted to non-employees are re-measured at each reporting date until the award is vested.

The Company accounts for stock issued as compensation in connection with business combinations based on the fair value of the Company's common stock on the date of issuance.

Advertising

Advertising expenses are expensed as incurred. The Company incurred advertising expenses of \$0.6 million, \$0.6 million and \$0.5 million during the years ended December 31, 2018, 2017 and 2016, respectively.

Comprehensive loss

Comprehensive loss is composed of two components: net loss and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' equity, but are excluded from net loss. The Company's other comprehensive income (loss) consists of unrealized gains or losses on investments in available-for-sale securities.

Net loss per share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury stock method. Potentially dilutive securities, consisting of preferred stock, options to purchase common stock, common stock warrants, RSUs and PRSUs, are considered to be common stock equivalents and were excluded from the calculation of diluted net loss per share because their effect would be antidilutive for all periods presented.

Recent accounting pronouncements

The Company evaluates all Accounting Standards Updates ("ASUs") issued by the FASB for consideration of their applicability. ASUs not included in the disclosures in this report were assessed and determined to be either not applicable or are not expected to have a material impact on the Company's consolidated financial statements.

Recently issued accounting pronouncements not yet adopted

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under Accounting Standards Codification ("ASC") 606 when the counterparty is a customer. In addition, Topic 808 precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. This guidance will be effective for the Company beginning January 1, 2020. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)*, which replaces the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects expected credit losses. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019, with early adoption permitted for the fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* and in July 2018 issued ASU 2018-10, *Codification Improvements to Topic 842, Leases* and ASU 2018-11, *Leases (Topic 842): Targeted Improvements* (the foregoing ASUs collectively referred to as "Topic 842"). Under the new guidance, lessees are required to recognize a lease liability and a right-of-use asset for all leases (with the exception of short-term leases) at the commencement date and also requires expanded disclosures about leasing arrangements. Topic 842 is effective for annual and interim periods beginning on or after December 15, 2018 and early adoption is permitted. Entities may initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

The Company is evaluating the final effect that Topic 842 and related standards will have on its consolidated financial statements, related disclosures and ongoing financial reporting, but expects implementation of Topic 842 to result in the recognition of material right of use assets and corresponding lease liabilities in its consolidated balance sheets as of the implementation of Topic 842 on January 1, 2019, principally relating to facilities leases. The Company does not have any material embedded leases and the implementation of Topic 842 is primarily focused on the treatment of the Company's previously identified leases. As of December 31, 2018, the Company's total future undiscounted capital lease payments were \$3.5 million and future undiscounted non-cancelable minimum operating lease payments, net of subleases were \$78.4 million

Recently adopted accounting pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, designed to enable users of financial statements to better understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. On January 1, 2018, the Company adopted the provisions of Topic 606 using the modified retrospective method. From adoption to date, the Company has recognized all its revenue from contracts with customers within the scope of Topic 606. In connection with the adoption, the Company recognized the cumulative effect of initially applying this standard as an adjustment to retained earnings on the date of adoption. Comparative information prior to the date of adoption has not been restated and continues to be reported under the accounting standards in effect for those periods.

In connection with the adoption of Topic 606, the Company amended its revenue recognition policy to provide for the recognition of certain variable consideration related to diagnostic tests that was previously deferred pending cash collection. Under Topic 606, the Company records variable consideration based on an estimate of the consideration to which it will be entitled.

The Company recognizes revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration it expects to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers.

Diagnostic tests

The majority of the Company's revenue is generated from genetic testing services that provide analysis and associated interpretation of the sequencing of parts of the genome. Test orders are placed under signed requisitions, and the Company often enters into contracts with institutions (e.g., hospitals and clinics) and insurance companies that include pricing provisions under which such tests are billed. Billing terms are generally net thirty days.

While the transaction price of diagnostic tests is originally established either via contract or pursuant to the Company's standard list price, the Company often provides concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which the Company will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur. Making these estimates requires significant judgments based upon such factors as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. These judgments are reviewed quarterly and revenue recognized is updated, as necessary, until the Company's obligations are fully settled.

In connection with some diagnostic test orders, the Company offers limited re-requisition rights ("Re-Requisition Rights") that are considered distinct at contract inception, and therefore certain diagnostic test orders contain two performance obligations, the performance of the original test and the Re-Requisition Rights. When Re-Requisition Rights are granted, the Company allocates the transaction price to each performance obligation based on the relative estimated standalone selling prices. In order to comply with loss contract rules, the allocations are adjusted, if necessary, to ensure the amount deferred for Re-Requisition Rights is no less than the estimated cost of fulfilling the Company's related obligations.

The Company looks to transfer of control in assessing timing of recognition of revenue in connection with each performance obligation. In general, revenue in connection with diagnostic tests is recognized upon delivery of the underlying clinical report or when the report is made available on the Company's web portal. Outstanding performance obligations pertaining to orders received but for which the underlying report has not been issued are generally satisfied within a thirty-day period. Revenue in connection with Re-Requisition Rights is recognized as the rights are exercised or expire unexercised, which is generally within ninety days of initial deferral.

Other contracts

The Company also enters into collaboration and genome network contracts. Collaboration agreements provide customers with diagnostic testing and related data aggregation reporting services that are provided over the contract term. Collaboration revenue is recognized as the testing and reporting services are delivered to the customer. Genome network offerings consist of subscription services related to a proprietary software platform designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis and treatment of hereditary disease. Such services are recognized on a straight-line basis over the subscription periods.

Amounts due under collaboration and genome network agreements are typically billable on net thirty-day terms.

3. Revenue, accounts receivable and deferred revenue

As described in Note 2, "Summary of significant accounting policies," the Company adopted Topic 606 effective January 1, 2018. In connection with the adoption the Company utilized the following practical expedients and exemptions:

- Certain information about remaining performance obligations is not disclosed because the underlying contracts have an original expected duration of one year or less.
- Costs to obtain or fulfill a contract are expensed when incurred because the amortization period would have been one year or less.
- No adjustments to promised consideration were made for financing as the Company expects, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

The adoption of Topic 606 resulted in a cumulative-effect adjustment to accounts receivable and accumulated deficit of \$11.2 million as of January 1, 2018 primarily related to the recognition of uncollected

diagnostic test variable consideration as of the date of adoption. Test revenue without adoption of Topic 606 for the year ended December 31, 2018 includes cash collections related to accounts receivable recorded as of January 1, 2018 in connection with the Topic 606 cumulative-effect adjustment.

The effect of the adoption of Topic 606 on financial statement line items in the Company's consolidated statement of operations for the year ended December 31, 2018, and the Company's consolidated balance sheet as of December 31, 2018 was as follows (in thousands, except per share amounts):

	Year Ended December 31, 2018		
	As Reported	Without Adoption of Topic 606	Effect of Adoption Higher/(Lower)
	Test revenue	\$ 144,560	\$ 144,222
Net loss	\$ (129,355)	\$ (129,693)	\$ 338
Net loss per share, basic and diluted	\$ (1.94)	\$ (1.94)	\$ —

	As of December 31, 2018		
	As Reported	Without Adoption of Topic 606	Effect of Adoption Higher/(Lower)
	Accounts receivable	\$ 26,296	\$ 14,150
Accumulated deficit	\$ (516,712)	\$ (528,291)	\$ 11,579
Stockholders' equity	\$ 161,839	\$ 150,260	\$ 11,579

Disaggregation of revenue

Test revenue is generated from sales of diagnostic tests to three groups of customers: institutions, such as hospitals, clinics and partners; patients who pay directly; and patients' insurance carriers. Amounts billed and collected, and the timing of collections, vary based on whether the payer is an institution, an insurance carrier or a patient. Other revenue consists principally of revenue recognized under collaboration and genome network agreements.

The following table includes the Company's revenues as disaggregated by payer category (in thousands):

	Year Ended December 31,	
	2018	2017 ⁽¹⁾
Test revenue:		
Institutions	\$ 34,618	\$ 17,238
Patient - direct	13,589	5,638
Patient - insurance	96,353	42,293
Total test revenue	144,560	65,169
Other revenue	3,139	3,052
Total revenue	\$ 147,699	\$ 68,221

⁽¹⁾ As noted above, prior period amounts are presented as originally reported based upon the accounting standards in effect for those periods.

Included in revenue in the Company's consolidated statements of operations for the year ended December 31, 2018 was \$0.3 million that was included in deferred revenue at January 1, 2018.

The Company recognizes revenue related to billings based on estimates of the amount that will ultimately be realized. The estimate of the transaction price of test revenue is based on many factors such as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. Cash collections for certain tests delivered may differ from rates originally estimated. As a result of new information, the Company updated its estimate of the amounts to be recognized for previously delivered tests which resulted in

an additional \$4.5 million of test revenue for the year ended December 31, 2018. These changes in estimates decreased the Company's loss from operations by \$4.5 million and decreased basic and diluted net loss per share by approximately \$0.07 for the year ended December 31, 2018.

Accounts receivable

The majority of the Company's accounts receivable represents amounts billed to institutions (e.g., hospitals, clinics) and estimated amounts to be collected from third-party insurance payers for test revenue recognized. Also included is amounts due under the terms of collaboration and genome network agreements for diagnostic testing and data aggregation reporting services provided and proprietary platform access rights transferred.

Deferred revenues

The Company records deferred revenues when cash payments are received or due in advance of its performance related to one or more performance obligations. The amounts deferred to date primarily consist of consideration received pertaining to the estimated exercise of certain Re-Requisition Rights. The Company defers revenue related to Re-Requisition Rights in amounts no less than the estimated cost of fulfilling its related obligations. The Company recognizes revenue related to Re-Requisition Rights as the rights are exercised or expire unexercised, which is generally within 90 days of initial deferral.

4. Business combinations

AltaVoice

On January 6, 2017, the Company acquired AltaVoice (formerly PatientCrossroads, Inc.), a privately-owned patient-centered data company with a global platform for collecting, curating, coordinating and delivering safeguarded data from patients and clinicians. The acquisition, complemented by several other strategic partnerships, expanded the Company's genome network, designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis, and treatment of hereditary disease. Pursuant to the terms of the Stock Purchase Agreement, the Company acquired all of the outstanding shares of AltaVoice for total purchase consideration of \$12.4 million, payable in the Company's common stock, as follows:

- (a) payment of \$5.5 million through the issuance of 641,126 shares of the Company's common stock;
- (b) payment of \$5.0 million in the Company's common stock, payable on March 31, 2018, with the common shares deliverable equal to \$5.0 million divided by the trailing average share price of the Company's common stock for the 30 days preceding March 31, 2018. This payment was made in April 2018 through the issuance of 716,332 shares of the Company's common stock;
- (c) payment of \$5.0 million in the Company's common stock, which was contingently payable on March 31, 2018 if a milestone based on a certain threshold of revenue was achieved during 2017, with the shares deliverable equal to \$5.0 million divided by the trailing average share price of the Company's common stock for the 30 days preceding March 31, 2018. As the foregoing milestone was not achieved, there was a new contingent milestone based on achieving a revenue target during 2017 and 2018. Since this new contingent milestone was achieved, on March 31, 2019, a payment of \$5.0 million in the Company's common stock will be payable. The actual payout is dependent upon meeting the 2017 and 2018 revenue targets (capped at \$14.0 million) times 75% less \$5.5 million. This formula in effect caps the possible payout amount at \$5.0 million in the Company's common shares. The number of shares to be issued will be equal to the payout amount divided by the trailing average share price of the Company's common stock for the 30 days preceding March 31, 2019.

The first payment of \$5.5 million was classified as equity. The second payment was discounted to \$4.7 million as of the acquisition date, recorded as a liability, and was accreted to fair value at each reporting date until the extinguishment of the liability in April 2018. The third payment, representing contingent consideration, was determined to have a fair value of \$2.2 million as of the acquisition date and was recorded as a liability. In accordance with ASC Topic 805, *Business Combinations*, the contingent consideration of \$2.2 million was remeasured to fair value at each reporting date until the contingency was resolved, with changes in fair value recognized in earnings.

For the second payment, the acquisition-date fair value was \$4.7 million, and the Company recorded accretion gains (losses) of \$1.6 million and \$(0.2) million in other income (expense), net, for the years ended December 31, 2018 and 2017, respectively. The accretion gains in 2018 resulted from an adjustment to the value of

the second payment as of March 31, 2018, and principally reflected the difference between the value of the common shares deliverable, based upon the closing price of the Company's stock on March 29, 2018, and the value per share used to calculate the number of common shares deliverable. The accretion losses in 2017 resulted from adjustments to the discounted value of the second payment, reflecting the passage of time.

For the third payment, the acquisition-date fair value was \$2.2 million, and the Company recorded remeasurement losses of \$1.2 million and \$1.6 million in general and administrative expense for the years ended December 31, 2018 and 2017, respectively. The remeasurement losses in 2018 reflect updated estimations of fair value of the third payment, based upon achieving a revenue target during 2017 and 2018, as the milestone based on a certain threshold of revenue to be achieved during 2017 was not met. The principal inputs affecting those estimations have been updates to the Company's revenue forecasts and the passage of time.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed at the date of acquisition (in thousands):

Cash	\$	54
Accounts receivable		274
Prepaid expense and other assets		52
Non-compete agreement		286
Developed technology		570
Customer relationships		3,389
Total identifiable assets acquired		<u>4,625</u>
Accounts payable		(28)
Deferred revenue		(202)
Accrued expenses		(21)
Deferred tax liability		(1,422)
Total liabilities assumed		<u>(1,673)</u>
Net identifiable assets acquired		2,952
Goodwill		9,432
Net assets acquired	\$	<u><u>12,384</u></u>

Acquisition-related intangibles included in the above table are finite-lived. Customer relationships are being amortized on an accelerated basis, utilizing free cash flows, over a period of ten years. All other acquisition-related intangibles are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized, as follows (in thousands):

	Gross Purchased Intangible Assets	Estimated Useful Life (in Years)
Non-compete agreement	\$ 286	5
Developed technology	570	6
Customer relationships	3,389	10
	<u>\$ 4,245</u>	

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of AltaVoice resulted in \$9.4 million of goodwill which the Company believes consists principally of expected synergies to be realized by combining capabilities, technology and data to accelerate the use of genetic information for the diagnosis and treatment of hereditary diseases. In accordance with ASC 350, goodwill will not be amortized but will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes. The Company has finalized its assessment of fair value of the assets and liabilities assumed at the acquisition date.

Ommdom

On June 11, 2017, the Company acquired Ommdom, Inc. (“Ommdom”), a privately held company that develops, commercializes and sells hereditary risk assessment and management software, including CancerGene Connect, a cancer genetic counseling platform. The acquisition expanded Invitae’s suite of genome management offerings designed to help patients and clinicians use genetic information as part of mainstream medical care. CancerGene Connect is a platform for collecting and managing genetic family histories.

Pursuant to the terms of a Stock Exchange Agreement, the Company acquired all of the outstanding shares of Ommdom for consideration of \$6.1 million, payable entirely in the Company’s common stock. There was no cash consideration nor any contingent payments associated with the acquisition, other than a hold-back amount of \$0.6 million. Per the terms of the agreement, the Company was obligated to issue shares of its common stock as follows:

- (a) payment of \$5.5 million through the issuance of 600,108 shares of the Company’s common stock on the acquisition date; and
- (b) payment of \$0.6 million through the issuance of 66,582 shares of the Company’s common stock, representing a hold-back amount, and payable on the twelve-month anniversary of the acquisition date.

The first payment of \$5.5 million was classified as equity. The second payment of \$0.6 million was recorded as a stock payable liability on the acquisition date and was reclassified to equity upon the issuance of 66,582 shares of the Company’s common stock in June 2018.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed at the date of acquisition (in thousands):

Cash	\$	53
Accounts receivable		10
Prepaid expense and other assets		4
Trade name		13
Developed technology		2,335
Customer relationships		147
Total identifiable assets acquired		2,562
Accounts payable		(16)
Accrued expenses		(17)
Deferred tax liability		(434)
Total liabilities assumed		(467)
Net identifiable assets acquired		2,095
Goodwill		4,045
Net assets acquired	\$	6,140

Finite-lived intangibles included in the above table are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized, as follows (in thousands):

	Gross Purchased Intangible Assets	Estimated Useful Life (in Years)
Trade name	\$ 13	5
Developed technology	2,335	5
Customer relationships	147	5
	\$ 2,495	

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Ommdom resulted in the recognition of \$4.0 million of goodwill which the Company believes consists principally of expected synergies to be realized by expanding the Company's suite of genome management offerings. In accordance with ASC 350, goodwill will not be amortized but rather will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes. The Company has finalized its assessment of fair value of the assets and liabilities assumed at the acquisition date.

Good Start Genetics

On August 4, 2017, the Company acquired 100% of the fully diluted equity of Good Start, a privately held molecular diagnostics company focused on preimplantation and carrier screening for inherited disorders. The acquisition of Good Start was intended to further Invitae's plan to create a comprehensive genetic information platform providing high-quality, affordable genetic information coupled with world-class clinical expertise to inform healthcare decisions throughout every stage of an individual's life. The purchase consideration for the Good Start acquisition consisted of the assumption of the net liabilities of Good Start of \$24.4 million at the acquisition date.

Immediately subsequent to the acquisition of Good Start, the Company paid \$18.4 million in cash to settle outstanding notes payable, accrued interest and related costs. In addition, and immediately subsequent to the acquisition, the Company settled outstanding convertible promissory notes payable through:

- (a) payment of \$11.9 million through the issuance of 1,148,283 shares of the Company's common stock; and
- (b) payment of \$3.6 million through the issuance of 343,986 shares of the Company's common stock, representing a hold-back amount payable on the one-year anniversary of the acquisition date. In September 2018, the Company issued 212,260 shares in partial payment of the hold-back amount payable. The remainder of the hold-back amount payable, approximately \$1.3 million as of December 31, 2018, will be settled upon resolution of outstanding claims from Good Start customers, of which \$0.6 million was settled in January 2019.

Also in connection with the acquisition of Good Start and immediately subsequent to the acquisition, the Company paid bonuses to certain members of Good Start's management team through:

- (a) payment of \$0.9 million through the issuance of 83,025 shares of the Company's common stock; and
- (b) payment of \$0.4 million through the issuance of 37,406 shares of the Company's common stock, representing a hold-back amount payable on the one-year anniversary of the acquisition date. In September 2018, the Company issued 27,784 shares in partial payment of the hold-back amount payable to settle bonuses to Good Start's management team. The remainder of the hold-back amount payable, approximately \$0.2 million as of December 31, 2018, will be settled upon resolution of outstanding claims from Good Start customers, of which \$0.1 million was settled in January 2019.

These bonus payments were recorded as general and administrative expense.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill.

At acquisition date, the Company also recorded \$4.8 million as a provisional amount for a deferred tax liability because certain information and analysis related to Good Start's historical net operating losses that could have affected the Company's initial valuation was still being obtained or reviewed at that time. This provisional amount for the deferred tax liability was subsequently reversed during the fourth quarter of 2017 based on the results of further analysis of Good Start's historical net operating losses.

The following table summarizes the fair values of assets acquired and liabilities assumed at the date of acquisition (in thousands):

Cash and restricted cash	\$	1,381
Accounts receivable		2,246
Prepaid expense and other assets		1,579
Property and equipment		1,320
Trade name		460
Developed technology		5,896
Customer relationships		7,830
Total identifiable assets acquired		<u>20,712</u>
Accounts payable		(5,418)
Accrued expenses		(6,802)
Notes payable		(17,904)
Convertible promissory notes payable		(15,430)
Other liabilities		(222)
Total liabilities assumed		<u>(45,776)</u>
Net identifiable assets acquired		(25,064)
Goodwill		25,064
Net assets acquired	\$	<u><u>—</u></u>

During the year ended December 31, 2018, the Company recorded adjustments to its accounting for the amount recorded as accounts receivable at acquisition. Accordingly, the fair value of accounts receivable was decreased by \$0.7 million during the year ended December 31, 2018, with corresponding increases to goodwill.

Customer relationships are being amortized on an accelerated basis, utilizing free cash flows, over a period of eight years. All other finite-lived intangibles included in the above table are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized, as follows (in thousands):

	Gross Purchased Intangible Assets	Estimated Useful Life (in Years)
Trade name	\$ 460	3
Developed technology	5,896	5
Customer relationships	7,830	8
	<u>\$ 14,186</u>	

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Good Start resulted in the recognition of \$25.1 million of goodwill which the Company believes consists principally of expected synergies to be realized by expanding the Company's suite of genome management offerings. In accordance with ASC 350, goodwill will not be amortized but rather will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes. The Company has finalized its assessment of fair value of the assets and liabilities assumed at the acquisition date.

CombiMatrix

On November 14, 2017, the Company completed its acquisition of CombiMatrix in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of July 31, 2017 (the "Merger Agreement"), by and among the Company, Coronado Merger Sub, Inc., a wholly owned subsidiary of the Company ("Merger Sub"), and CombiMatrix, pursuant to which Merger Sub merged with and into CombiMatrix, with CombiMatrix surviving as a wholly owned subsidiary of the Company (the "Merger").

At the closing of the Merger, the Company issued shares of its common stock to (i) CombiMatrix's common stockholders, at an exchange ratio of 0.8692 of a share of the Company's common stock (the "Merger Exchange

Ratio”) for each share of CombiMatrix common stock outstanding immediately prior to the Merger, (ii) CombiMatrix’s Series F preferred stockholders, at the Merger Exchange Ratio for each share of CombiMatrix common stock underlying Series F preferred stock outstanding immediately prior to the Merger, (iii) holders of outstanding and unexercised in-the-money CombiMatrix stock options, which were fully accelerated to the extent of any applicable vesting period and converted into the right to receive the number of shares of the Company’s common stock equal to the Merger Exchange Ratio multiplied by the number of shares of CombiMatrix common stock issuable upon exercise of such option, minus the number of shares of the Company’s common stock determined by dividing the aggregate exercise price for such option by \$9.491, and (iv) holders of outstanding and unsettled CombiMatrix restricted stock units, which were fully accelerated to the extent of any applicable vesting period and converted into the right to receive a number of shares of the Company’s common stock determined by multiplying the number of shares of CombiMatrix common stock that were subject to such restricted stock unit by the Merger Exchange Ratio.

In addition, at the closing of the Merger, (a) all outstanding and unexercised out-of-the money CombiMatrix stock options were cancelled and terminated without the right to receive any consideration, (b) all CombiMatrix Series D Warrants and Series F Warrants outstanding and unexercised immediately prior to the closing of the Merger were assumed by the Company and converted into warrants to purchase the number of shares of the Company’s common stock determined by multiplying the number of shares of CombiMatrix common stock subject to such warrants by the Merger Exchange Ratio, and with the exercise price adjusted by dividing the per share exercise price of the CombiMatrix common stock subject to such warrants by the Merger Exchange Ratio, and (c) certain entitlements under CombiMatrix’s executive compensation transaction bonus plan (the “Transaction Bonus Plan”) were paid in shares of the Company’s common stock or RSUs to be settled in shares of the Company’s common stock. All outstanding and unexercised CombiMatrix Series A, Series B, Series C, Series E, and PIPE warrants were repurchased by CombiMatrix prior to closing pursuant to that certain CombiMatrix Common Stock Purchase Warrants Repurchase Agreement dated July 11, 2016.

Pursuant to the Merger Agreement, the Company issued an aggregate of 2,703,389 shares of its common stock as follows:

- (a) payment of \$20.5 million through the issuance of 2,611,703 shares of the Company’s common stock to holders of CombiMatrix common stock outstanding;
- (b) payment of \$0.7 million through the issuance of 85,219 shares of the Company’s RSUs to holders of outstanding and unsettled CombiMatrix restricted stock units;
- (c) payment of \$0.1 million through the issuance of 3,323 shares of the Company’s common stock to holders of outstanding and unexercised in-the-money CombiMatrix stock options; and
- (d) payment of \$0.1 million through the issuance of 3,144 shares of the Company’s common stock to holders of CombiMatrix Series F preferred stock.

In addition, and pursuant to the Merger Agreement, the Company issued warrants to purchase an aggregate of 2,077,273 shares of its common stock as follows:

- (a) payment of \$7.4 million through the issuance of warrants to purchase a total of 1,739,689 shares of the Company’s common stock in exchange for all outstanding CombiMatrix Series F warrants; and
- (b) payment of \$1,000 through the issuance of warrants to purchase a total of 337,584 shares of the Company’s common stock in exchange for all outstanding CombiMatrix Series D warrants.

In connection with the acquisition of CombiMatrix, the Company paid bonuses to certain members of CombiMatrix’s management team through:

- (a) payment of \$1.7 million through the issuance of common stock and RSUs totaling 214,976 shares of the Company’s common stock to settle payments pursuant to CombiMatrix’s executive compensation transaction bonus plan (the “Transaction Bonus Plan”), recorded as post-combination compensation expense and included in general and administrative expense; and
- (b) payment of \$0.2 million through the issuance of 22,966 shares of the Company’s common stock to settle payments pursuant to the Transaction Bonus Plan, recorded as an assumed liability at the acquisition date.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed at the date of acquisition (in thousands):

Cash and restricted cash	\$	1,333
Accounts receivable		4,118
Prepaid expense and other assets		1,299
Property and equipment		437
Other assets - non current		30
Favorable leases		247
Trade name		103
Patent licensing agreement		496
Developed technology		3,162
Customer relationships		12,397
Total identifiable assets acquired		<u>23,622</u>
Accounts payable		(276)
Accrued expenses		(3,925)
Deferred tax liability		(2,862)
Other liabilities		(180)
Total liabilities assumed		<u>(7,243)</u>
Net identifiable assets acquired		16,379
Goodwill		11,554
Net assets acquired	\$	<u>27,933</u>

During the year ended December 31, 2018, upon the completion of the Company's analysis of CombiMatrix's historical net operating losses, the Company recorded a deferred tax liability of \$2.9 million with corresponding increases to goodwill. The \$2.9 million net deferred tax liability represents the excess of the financial reporting over tax basis in acquired intangibles over the amount of CombiMatrix's historical net operating loss carryovers that were determined to be available to offset future income due to change in ownership operating loss carryover limitation rules under Internal Revenue Code section 382.

Customer relationships are being amortized on an accelerated basis, utilizing free cash flows, over a period of eleven years. All other finite-lived intangibles included in the above table are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized, as follows (in thousands):

	Gross Purchased Intangible Assets	Estimated Useful Life (in Years)
Favorable leases	\$ 247	2
Trade name	103	1
Patent licensing agreement	496	15
Developed technology	3,162	4
Customer relationships	12,397	11
	<u>\$ 16,405</u>	

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of CombiMatrix resulted in the recognition of \$11.6 million of goodwill which the Company believes consists principally of expected synergies to be realized by expanding the Company's suite of genome management offerings. In accordance with ASC 350, goodwill will not be amortized but rather will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes. The Company has finalized its assessment of fair value of the assets and liabilities assumed at the acquisition date.

5. Goodwill and intangible assets

Goodwill

Details of the Company's goodwill for the year ended December 31, 2018 are as follows (in thousands):

	AltaVoice	Ommdom	Good Start	CombiMatrix	Total
Balance as of December 31, 2017	\$ 9,432	\$ 4,045	\$ 24,406	\$ 8,692	\$ 46,575
Goodwill adjustment	—	—	658	2,862	3,520
Balance as of December 31, 2018	<u>\$ 9,432</u>	<u>\$ 4,045</u>	<u>\$ 25,064</u>	<u>\$ 11,554</u>	<u>\$ 50,095</u>

The goodwill adjustments were principally due to changes in the fair value of accounts receivable for Good Start as well as the recognition of a \$2.9 million deferred tax liability for CombiMatrix resulting from the completion of the Company's analysis of historical net operating losses.

Intangible assets

The following table presents details of the Company's finite-lived intangible assets as of December 31, 2018 (in thousands):

	Cost	Accumulated Amortization	Net	Weighted Average Useful Life (in Years)	Weighted Average Estimated Remaining Useful Life (in Years)
Customer relationships	\$ 23,763	\$ (2,783)	\$ 20,980	10.0	8.6
Developed technology	11,963	(3,482)	8,481	4.8	3.4
Non-compete agreement	286	(114)	172	5.0	3.0
Trade name	576	(329)	247	2.7	1.4
Patent licensing agreement	496	(37)	459	15.0	13.9
Favorable leases	247	(117)	130	2.2	1.1
	<u>\$ 37,331</u>	<u>\$ (6,862)</u>	<u>\$ 30,469</u>	8.2	6.8

Acquisition-related intangibles included in the above table are finite-lived. Customer relationships are being amortized on an accelerated basis, in proportion to estimated cash flows, over periods ranging from five to eleven years. All other acquisition-related intangibles are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are realized. Amortization expense was \$5.0 million, \$1.8 million, and nil for the years ended December 31, 2018, 2017, and 2016, respectively. Intangible assets are carried at cost less accumulated amortization. Amortization expense is recorded to research and development, sales and marketing and general and administrative expense.

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of December 31, 2018 (in thousands):

	<u>Amount</u>
2019	\$ 5,250
2020	5,525
2021	5,829
2022	4,124
2023	3,111
Thereafter	6,630
Total estimated future amortization expense	<u>\$ 30,469</u>

6. Balance sheet components

Property and equipment, net

Property and equipment consisted of the following (in thousands):

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Leasehold improvements	\$ 13,034	\$ 12,623
Laboratory equipment	22,149	17,705
Equipment under capital lease	7,129	11,446
Computer equipment	4,723	4,023
Software	2,594	2,520
Furniture and fixtures	784	569
Automobiles	20	20
Construction-in-progress	1,962	965
Total property and equipment, gross	<u>52,395</u>	<u>49,871</u>
Accumulated depreciation and amortization	(24,509)	(19,530)
Total property and equipment, net	<u>\$ 27,886</u>	<u>\$ 30,341</u>

Depreciation expense was \$8.5 million, \$7.2 million and \$6.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Accrued compensation and related expenses	\$ 7,917	\$ 7,406
Deferred revenue	761	307
Liabilities associated with business combinations	6,460	9,497
Liability associated with co-development agreement	2,000	—
Other	9,425	5,532
Total accrued liabilities	<u>\$ 26,563</u>	<u>\$ 22,742</u>

Other long-term liabilities

Other long-term liabilities consisted of the following (in thousands):

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Lease incentive obligation, non-current	\$ 3,280	\$ 3,831
Deferred rent, non-current	5,495	5,153
Liabilities associated with business combinations	—	3,779
Other non-current liabilities	181	677
Total other long-term liabilities	<u>\$ 8,956</u>	<u>\$ 13,440</u>

7. Fair value measurements

Financial assets and liabilities are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The authoritative guidance establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques is summarized as follows:

Level 1—Observable inputs such as quoted prices (unadjusted) for identical instruments in active markets.

Level 2—Observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-derived valuations whose significant inputs are observable.

Level 3—Unobservable inputs that reflect the reporting entity's own assumptions.

The following tables set forth the fair value of the Company's consolidated financial instruments that were measured at fair value on a recurring basis (in thousands):

	December 31, 2018						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	\$ 93,934	\$ —	\$ —	\$ 93,934	\$ 93,934	\$ —	\$ —
Certificates of deposit	300	—	—	300	—	300	—
Commercial paper	10,908	—	(1)	10,907	—	10,907	—
U.S. treasury notes	9,990	—	—	9,990	9,990	—	—
U.S. government agency securities	6,001	—	(4)	5,997	—	5,997	—
Total financial assets	\$ 121,133	\$ —	\$ (5)	\$ 121,128	\$ 103,924	\$ 17,204	\$ —
Financial liabilities:							
Contingent consideration				\$ 4,998	\$ —	\$ —	\$ 4,998
Total financial liabilities				\$ 4,998	\$ —	\$ —	\$ 4,998

	December 31, 2018	
Reported as:		
Cash equivalents	\$	101,395
Restricted cash		6,006
Marketable securities		13,727
Total cash equivalents, restricted cash, and marketable securities	\$	121,128
Accrued liabilities	\$	4,998

December 31, 2017

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	\$ 5,998	\$ —	\$ —	\$ 5,998	\$ 5,998	\$ —	\$ —
Certificates of deposit	300	—	—	300	300	—	—
U.S. treasury notes	12,010	—	(19)	11,991	11,991	—	—
U.S. government agency securities	46,451	—	(152)	46,299	—	46,299	—
Total financial assets	\$ 64,759	\$ —	\$ (171)	\$ 64,588	\$ 18,289	\$ 46,299	\$ —

Financial liabilities:

Contingent consideration				\$ 3,779	\$ —	\$ —	\$ 3,779
Total financial liabilities				\$ 3,779	\$ —	\$ —	\$ 3,779

December 31, 2017

Reported as:		
Cash equivalents		\$ 592
Restricted cash		5,406
Marketable securities		58,590
Total cash equivalents, restricted cash, and marketable securities		\$ 64,588
Accrued liabilities		\$ 3,779

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. The total fair value of investments with unrealized losses at December 31, 2018 was \$13.4 million. None of the available-for-sale securities held as of December 31, 2018 has been in a material continuous unrealized loss position for more than one year. At December 31, 2018, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered to be temporary. The Company believes it is more likely than not that investments in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not identified any other-than-temporary declines in market value and thus has not recorded any impairment charges on its financial assets other than on the convertible notes which are described in Note 8, "Investment in privately held company."

At December 31, 2018, the remaining contractual maturities of available-for-sale securities ranged from less than one to 4 months. For the years ended December 31, 2018, 2017 and 2016, there were no realized gains or losses on available-for-sale securities.

The Company's certificates of deposit, commercial paper, and debt securities of U.S. government agency entities are classified as Level 2 as they are valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third party data providers, including but not limited to benchmark yields, interest rate curves, reported trades, broker/dealer quotes and reference data.

The following table presents the Company's Level 3 financial instruments that are measured at fair value on a recurring basis (in thousands):

	Level 3	
	Contingent Consideration Liability	
Balance as of December 31, 2017	\$	3,779
Change in estimate of fair value		1,219
Balance as of December 31, 2018	\$	4,998

As of December 31, 2018, the Company had a contingent obligation of up to \$5.0 million payable in the Company's common stock to the former owners of AltaVoice in conjunction with the Company's acquisition of AltaVoice in January 2017. The contingency was dependent upon future revenues attributable to AltaVoice. If the revenue attributable to AltaVoice for the combined period of 2017 and 2018 was at least \$10 million, the Company would make a payment of up to \$5.0 million in the Company's common stock in March 2019. The Company estimated the fair value of the contingent consideration at \$2.2 million at the acquisition date in January 2017, based on a Monte Carlo simulation, as well as estimates of the 30-day trailing price of its stock at certain dates, its volatility assumptions and its revenue forecasts, all of which were significant inputs in the Level 3 measurement not supported by market activity. The value of the liability was subsequently remeasured to fair value at each reporting date. Changes in estimated fair value are recorded as general and administrative expense until the contingency is paid or expires. The change in the fair value of the contingent consideration between the acquisition date and December 31, 2018 was an increase of \$2.8 million.

The fair value of the Company's outstanding debt is estimated using the net present value of future debt payments, discounted at an interest rate that is consistent with market interest rates, which is a Level 2 input. The carrying amount of the Company's outstanding debt at December 31, 2018 approximated its fair value and as of December 31, 2017, the Company's debt carrying amount and fair value were as follows (in thousands):

	December 31, 2017	
	Carrying Amount	Fair Value
Debt	\$ 39,084	\$ 40,526

8. Investment in privately held company

On March 15, 2018, the Company entered into a collaboration agreement with KEW, Inc. ("KEW"), a privately held comprehensive genomic profiling company. The Company determined it had a variable interest in a VIE through its investment in a convertible note issued by KEW. During the year ended December 31, 2018, the Company incurred losses relating to this collaboration agreement with KEW of \$2.9 million which were recognized in general and administrative expenses in the Company's consolidated statements of operations. As of December 31, 2018, the Company fulfilled its obligations with respect to the collaboration agreement and there are no balances recorded in the Company's consolidated balance sheets pertaining to this arrangement.

9. Commitments and contingencies

Operating leases

In September 2015, the Company entered into a lease agreement for its headquarters and main production facility in San Francisco, California. This lease expires in July 2026 and the Company may renew the lease for an additional ten years. The Company has determined the lease term to be a ten-year period expiring in 2026. The lease term commenced when the Company took occupancy of the facility in February 2016. In connection with the execution of the lease, the Company provided a security deposit of approximately \$4.6 million which is included in restricted cash in the Company's consolidated balance sheets. Minimum annual rent under the lease is subject to increases based on stated rental adjustment terms. In addition, per the terms of the lease, the Company received a \$5.2 million lease incentive in the form of reimbursement from the landlord for a portion of the costs of leasehold improvements the Company has made to the facility. The assets purchased with the lease incentive are included in property and equipment, net, in the Company's consolidated balance sheets and the lease incentive is recognized as a reduction of rental expense on a straight-line basis over the term of the lease. At December 31, 2018, all of the lease incentive had been utilized by the Company and all related reimbursements had been received from the landlord. Aggregate future minimum lease payments for this facility at December 31, 2018 were approximately \$57.8 million.

Future minimum payments under non-cancelable operating leases and future minimum payments to be received from non-cancelable subleases as of December 31, 2018 are as follows (in thousands):

	<u>Amounts</u>
2019	\$ 10,948
2020	10,860
2021	11,109
2022	11,067
2023	8,898
Thereafter	<u>25,715</u>
Future non-cancelable minimum operating lease payments	78,597
Less: minimum payments to be received from non-cancelable subleases	(174)
Total future non-cancelable minimum operating lease payments, net	<u>\$ 78,423</u>

The following table summarizes rent expense related to non-cancelable operating leases (in thousands):

	<u>Year Ended December 31,</u>		
	<u>2018</u>	<u>2017</u>	<u>2016</u>
Rent expense	\$ 9,720	\$ 8,950	\$ 8,901
Sublease income	227	398	257
Rent expense, net of sublease income	<u>\$ 9,493</u>	<u>\$ 8,552</u>	<u>\$ 8,644</u>

Debt financing

In March 2017, the Company entered into a Loan and Security Agreement (the "2017 Loan Agreement") with a lender pursuant to which the Company borrowed an initial term loan of \$40.0 million, and received net proceeds of approximately \$39.7 million. Subject to certain conditions, the Company was eligible to borrow a second term loan pursuant to the 2017 Loan Agreement of \$20.0 million in the first quarter of 2018 and did so in March 2018, receiving net proceeds of approximately \$19.8 million.

In February 2018 and June 2018, the Company entered into amendments to the 2017 Loan Agreement (the "2018 Amendments") pursuant to which the Company, subject to certain conditions, was eligible to borrow a third term loan of \$20.0 million during the period from April 2, 2018 to December 31, 2018. Pursuant to the 2018 Amendments, since the third term loan became available and the Company did not draw upon the third term loan, a fee of 1% was applied to the difference between \$20.0 million and the amount drawn, or \$0.2 million.

Term loans under the amended 2017 Loan Agreement bore interest at a floating rate equal to an index rate plus 7.73%, where the index rate was the greater of 0.77% or the 30-day U.S. Dollar London Interbank Offered Rate ("LIBOR") as reported in *The Wall Street Journal*, with the floating rate resetting monthly subject to a floor of 8.5%.

The Company could make monthly interest-only payments until May 1, 2019 (or, subject to certain conditions, May 1, 2020), and thereafter monthly payments of principal and interest were required to fully amortize the borrowed amount by a final maturity date of March 1, 2022. A fee of 5% of each funded draw was due at the earlier of prepayment or loan maturity, a facility fee of 0.5% was due upon funding for each draw, and a prepayment fee of between 1% and 3% of the outstanding balance applied in the event of a prepayment. Concurrent with each term loan, the Company granted to the lender a warrant to acquire shares of the Company's common stock equal to the quotient of 3% of the funded amount divided by a per share exercise price equal to the lower of the average closing price for the previous ten days of trading (calculated on the day prior to funding) or the closing price on the day prior to funding. In connection with the initial term loan, in 2017, the Company issued the lender warrants to purchase 116,845 shares of common stock at an exercise price of \$10.27 per share. The Company classified these warrants as equity with a fair value of \$0.7 million. In connection with the second term loan, in 2018, the Company issued the lender warrants to purchase 85,482 shares of common stock at an exercise price of \$7.02 per share. The Company classified these warrants as equity with a fair value of \$0.4 million. All warrants issued pursuant to the amended 2017 Loan Agreement have a term of ten years from the date of issuance and include a cashless exercise provision.

In November 2018, the Company entered into a Note Purchase Agreement (the "2018 Note Purchase Agreement") pursuant to which the Company was eligible to borrow an aggregate principal amount up to \$200.0 million over a seven year maturity term which included an initial borrowing of \$75.0 million in November 2018. The Company received net proceeds of \$10.3 million after terminating and repaying the balance of its obligations of approximately \$64.7 million under the 2017 Loan Agreement and associated amendments with its previous lender. The Company incurred \$5.3 million of debt extinguishment costs upon terminating its previous debt facility which the Company recorded as other income (expense), net in its consolidated statements of operations during the year ended December 31, 2018.

At December 31, 2018, obligations under the 2018 Note Purchase Agreement were \$75.0 million which are required to be repaid to the lender in a balloon payment no later than 2025. If the Company repays prior to the three year anniversary following the initial borrowing, the amount due will be: 117.5% of the principal amount if payment is made within 12 months after the borrowing; 132.5% of the principal amount if payment is made between 12 and 24 months after the borrowing; and 145.0% of the principal amount if payment is made between 24 and 36 months after the borrowing.

The outstanding principal amount under the 2018 Note Purchase Agreement bears interest at a rate of 8.75% annually. In addition, beginning on January 1, 2020 and continuing until repayment or maturity of any outstanding principal, the Company will make quarterly payments of 0.5% of the Company's annual net revenues subject to a maximum annual amount of such payments of \$1.6 million which will be recognized as interest expense. Through the fixed interest charges and the quarterly revenue payments, the Company is required to pay total amounts to generate an 11% internal rate of return to the lender on any outstanding principal balances due in a lump-sum upon the repayment or maturity of any outstanding principal. During the year ended December 31, 2018, the 2018 Note Purchase Agreement bore interest at an average interest rate of 10.6%.

The 2018 Note Purchase Agreement contains quarterly covenants to achieve certain revenue levels as well as additional covenants, including limits on the Company's ability to dispose of assets, undergo a change of control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of its capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The Company's obligations under the 2018 Note Purchase Agreement are secured by a security interest on substantially all of its and certain of its subsidiaries' assets.

In connection with the 2018 Note Purchase Agreement, in November 2018, the Company entered into a Securities Purchase Agreement with the lender pursuant to which the Company issued 373,524 shares of its common stock at a price of \$13.39 per share for an aggregate amount of \$5.0 million. The share price paid by the lender was calculated based on the 15-day average closing share price prior to the issuance. The relative fair value method was used to allocate the proceeds between the common stock issued and the note proceeds; the fair value of the common stock issued to the lender was determined to be \$5.4 million.

Debt discounts, including debt issuance costs, related to the 2018 Note Purchase Agreement of \$0.7 million were recorded as a direct deduction from the debt liability and are being amortized to interest expense over the term of the 2018 Note Purchase Agreement. Future estimated payments under the 2018 Note Purchase Agreement as of December 31, 2018 are as follows (in thousands):

	<u>Amounts</u>
2019	\$ 6,654
2020	8,297
2021	8,279
2022	8,279
2023	8,279
Thereafter	89,998
Total remaining payments	<u>129,786</u>
Less: amount representing debt discount	(721)
Less: amount representing interest	(54,588)
Total non-current debt obligation	<u>\$ 74,477</u>

Interest expense related to the Company's debt financings was \$6.7 million, \$3.5 million and \$0.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Capital leases

The Company has entered into various capital lease agreements to obtain laboratory equipment. The terms of the Company's capital leases are typically three years and are secured by the underlying equipment. The portion of the future payments designated as principal repayment was classified as a capital lease obligation on the consolidated balance sheets.

Future payments under capital leases at December 31, 2018 were as follows (in thousands):

	<u>Amounts</u>
2019	\$ 2,087
2020	1,392
2021	21
Total capital lease obligations	<u>3,500</u>
Less: amount representing interest	(188)
Present value of net minimum capital lease payments	<u>3,312</u>
Less: current portion	(1,937)
Total non-current capital lease obligations	<u>\$ 1,375</u>

Interest expense related to capital leases was \$0.3 million, \$0.2 million and \$0.1 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Property and equipment under capital leases was \$7.1 million and \$11.4 million as of December 31, 2018 and 2017, respectively. Accumulated depreciation, collectively, on these assets was \$2.0 million and \$3.0 million at December 31, 2018 and 2017, respectively.

Guarantees and indemnifications

As permitted under Delaware law and in accordance with the Company's bylaws, the Company indemnifies its directors and officers for certain events or occurrences while the officer or director is or was serving in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company maintains director and officer liability insurance. This insurance allows the transfer of the risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company did not record any liabilities associated with these indemnification agreements at December 31, 2018 or December 31, 2017.

Other commitments

In the normal course of business, the Company enters into various purchase commitments primarily related to service agreements, laboratory supplies, and a co-development agreement. At December 31, 2018, the Company's total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were as follows (in thousands):

	Amount
2019	\$ 3,040
2020	3,040
2021	1,440
Total	<u>\$ 7,520</u>

In addition, in September 2018, the Company entered into a co-development agreement with a privately held genetics testing company. The co-development agreement grants the Company the right of first refusal to enter into an agreement for an acquisition of the entity in return for total fees of \$3.0 million over the term of the 12-month agreement, of which \$1.0 million has been paid by the Company as of December 31, 2018. The unpaid fees of \$2.0 million were paid in January 2019, and as of December 31, 2018, were recorded as an accrued liability in the Company's consolidated balance sheets.

Contingencies

The Company was not a party to any material legal proceedings at December 31, 2018, or at the date of this report. The Company may from time to time become involved in various legal proceedings arising in the ordinary course of business, and the resolution of any such claims could be material.

10. Stockholders' Equity

Common stock

As of December 31, 2018 and 2017, the Company had reserved shares of common stock, on an as-if converted basis, for issuance as follows (in thousands):

	As of December 31,	
	2018	2017
Options issued and outstanding	3,855	4,115
RSU awards issued and outstanding	4,031	2,387
Shares available for grant under stock option plans	118	2,397
Shares reserved for issuance under the 2015 Employee Stock Purchase Plan	278	308
Common stock underlying warrants	611	1,962
Common stock issuable upon conversion of preferred stock	3,459	3,459
Common stock underlying stock payable liabilities	132	689
Common stock payable as contingent consideration	452	551
Total	<u>12,936</u>	<u>15,868</u>

Private placement

In August 2017, in a private placement to certain accredited investors, the Company issued 5.2 million shares of its common stock at a price of \$8.50 per share, and 3.5 million shares of its Series A convertible preferred stock at a price of \$8.50 per share, for gross proceeds of approximately \$73.5 million and net proceeds of \$68.9 million. The Series A preferred stock is a non-voting common stock equivalent and conversion of the Series A preferred stock is prohibited if the holder exceeds a specified threshold of voting security ownership. The Series A preferred stock is convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like. The Series A Preferred Stock has the right to receive dividends first or simultaneously with payment of dividends on common stock, in an amount equal to the product of (i) the dividend payable on each share of common stock and (ii) the number of shares of common stock issuable upon conversion

of a share of Series A Preferred Stock. The Series A Preferred Stock has no voting rights except as required by law, as modified by the Company's Amended and Restated Certificate of Incorporation. In the event of any liquidation or dissolution of the Company, the Series A Preferred Stock is entitled to receive \$0.001 per share prior to the payment of any amount to any holders of capital stock of the Company ranking junior to the Series A Preferred Stock and thereafter shall participate pari passu with the holders of the Company's common stock (on an as-if-converted-to-common-stock basis). During January and February 2019, 1.1 million shares of Series A convertible preferred stock were converted to 1.1 million shares of common stock.

Public offering

In April 2018, the Company issued, in an underwritten public offering, an aggregate of 12.8 million shares of its common stock at a price of \$4.50 per share, for gross proceeds of \$57.5 million and net proceeds of \$53.5 million.

2018 Sales Agreement

In August 2018, the Company entered into a Common Stock Sales Agreement (the "2018 Sales Agreement") with Cowen and Company, LLC ("Cowen"), under which the Company may offer and sell from time to time at its sole discretion shares of its common stock through Cowen as its sales agent, in an aggregate amount not to exceed \$75.0 million. Cowen may sell the shares by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including without limitation sales made directly on The New York Stock Exchange, and also may sell the shares in privately negotiated transactions, subject to the Company's prior approval. The Company is obligated to pay Cowen a commission equal to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2018 Sales Agreement. During the year ended December 31, 2018, the Company issued a total of 4.3 million shares of common stock under the 2018 Sales Agreement for aggregate gross proceeds of \$61.1 million and net proceeds of \$58.9 million.

Common stock warrants

As of December 31, 2018, the Company had outstanding warrants to purchase common stock as follows:

Warrant	Issuance Date	Expiration Date	Exercise Price Per Share	Number of Shares of Common Stock Underlying Warrants
Warrants issued in exchange for CombiMatrix Series F warrants	November 2017	March 2021	\$ 5.95	408,548
Warrants issued to lender under 2017 Loan Agreement	March 2017	March 2027	\$ 10.27	116,845
Warrants issued to lender under 2017 Loan Agreement - 2018 Amendments	March 2018	March 2028	\$ 7.02	85,482
				610,875

The exercise price of warrants issued in exchange for CombiMatrix Series F warrants was determined pursuant to the terms of the Merger Agreement (See Note 4, "Business Combinations"). The CombiMatrix Series D warrants expired during the year ended December 31, 2018. The exercise price of the warrants issued to the lender under the 2017 Loan Agreement was the closing price of the Company's common stock on the date of the agreements. During the year ended December 31, 2018, the Company received \$6.5 million from exercises 1.0 million shares of common stock under these warrants.

11. Stock incentive plans

Stock incentive plans

In 2010, the Company adopted the 2010 Incentive Plan (the "2010 Plan"). The 2010 Plan provides for the granting of stock-based awards to employees, directors and consultants under terms and provisions established by the Board of Directors. Under the terms of the 2010 Plan, options may be granted at an exercise price not less than fair market value. For employees holding more than 10% of the voting rights of all classes of stock, the exercise prices for incentive and nonstatutory stock options must be at least 110% of fair market of the common stock on the grant date, as determined by the Board of Directors. The terms of options granted under the 2010 Plan may not exceed ten years.

In January 2015, the Company adopted the 2015 Stock Incentive Plan (the “2015 Plan”), which became effective upon the closing of the Company’s initial public offering (“IPO”). Shares outstanding under the 2010 Plan were transferred to the 2015 Plan upon effectiveness of the 2015 Plan. The 2015 Plan provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 through January 1, 2025. In addition, shares subject to awards under the 2010 Plan that are forfeited or terminated will be added to the 2015 Plan. The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock units, stock appreciation rights and other forms of equity compensation, all of which may be granted to employees, including officers, non-employee directors and consultants. Additionally, the 2015 Plan provides for the grant of cash-based awards.

Options granted generally vest over a period of four years. Typically, the vesting schedule for options granted to newly hired employees provides that 1/4 of the award vests upon the first anniversary of the employee’s date of hire, with the remainder of the award vesting monthly thereafter at a rate of 1/48 of the total shares subject to the option. All other options typically vest in equal monthly installments over the four-year vesting schedule.

RSUs generally vest over a period of three years. Typically, the vesting schedule for RSUs provides that one third of the award vests upon each anniversary of the grant date.

In February 2016, the Company granted PRSUs under the 2015 Plan, which PRSUs could be earned based on the achievement of specified performance conditions measured over a period of approximately 12 months. In February 2017, upon the Audit Committee’s determination of the level of achievement, 352,045 fully vested stock units were awarded to holders of PRSUs. The Company has not granted any PRSUs since 2016.

Based on its evaluations of the probability of achieving performance conditions, the Company recorded stock-based compensation expense of nil, \$0.4 million, and \$1.9 million for the years ended December 31, 2018, 2017, and 2016, respectively, related to the PRSUs.

Activity under the 2010 Plan and the 2015 Plan is set forth below (in thousands, except per share amounts and years):

	Shares Available For Grant	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Balance at December 31, 2017	2,397	4,115	\$ 8.51	7.6	\$ 5,128
Additional shares reserved	754	—			
Options granted	(260)	260	\$ 8.50		
Options cancelled	169	(169)	\$ 9.35		
Options exercised	—	(351)	\$ 7.73		
RSUs granted	(3,282)	—			
RSUs cancelled	340	—			
Balance at December 31, 2018	<u>118</u>	<u>3,855</u>	\$ 8.54	6.8	\$ 9,927
Options exercisable at December 31, 2018		<u>2,737</u>	\$ 8.27	6.4	\$ 7,787
Options vested and expected to vest at December 31, 2018		<u>3,710</u>	\$ 8.52	6.8	\$ 9,626

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company’s common stock for stock options that were in-the-money.

The weighted-average fair value of options to purchase common stock granted was \$4.87, \$5.82 and \$6.18 in the years ended December 31, 2018, 2017 and 2016, respectively. The weighted-average fair value of RSUs granted was \$7.46, \$10.03 and \$9.80 in the years ended December 31, 2018, 2017 and 2016, respectively. No PRSUs were granted in the years ended December 31, 2018 or 2017 and the weighted average fair value of PRSUs granted in the year ended December 31, 2016 was \$6.50.

The total grant-date fair value of options to purchase common stock vested was \$5.9 million, \$6.9 million and \$5.6 million in the year ended December 31, 2018, 2017, and 2016, respectively.

The intrinsic value of options to purchase common stock exercised was \$1.7 million, \$2.1 million and \$1.4 million in the years ended December 31, 2018, 2017 and 2016, respectively.

The following table summarizes RSU activity for the year ended December 31, 2018 (in thousands, except per share data:

	Number of Shares	Weighted-Average Grant Date Fair Value
Balance at December 31, 2017	2,387	\$ 9.91
RSUs granted	3,282	\$ 7.46
RSUs vested	(1,298)	\$ 8.84
RSUs cancelled	(340)	\$ 8.84
Balance at December 31, 2018	<u>4,031</u>	<u>\$ 8.35</u>

2015 employee stock purchase plan

In January 2015, the Company adopted the 2015 Employee Stock Purchase Plan (the “ESPP”), which became effective upon the closing of the IPO. Employees participating in the ESPP may purchase common stock at 85% of the lesser of the fair market value of common stock on the purchase date or last trading day preceding the offering date. At December 31, 2018, cash received from payroll deductions pursuant to the ESPP was \$0.6 million.

The ESPP provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 and continuing through January 1, 2025. At December 31, 2018, a total of 277,577 shares of common stock are reserved for issuance under the ESPP.

Stock-based compensation

The Company uses the grant date fair value of its common stock to value both employee and non-employee options when granted. The Company revalues non-employee options each reporting period using the fair market value of the Company’s common stock as of the last day of each reporting period.

In determining the fair value of stock options and ESPP purchases, the Company uses the Black-Scholes option-pricing model and, for stock options, the assumptions discussed below. Each of these inputs is subjective and its determination generally requires significant judgment. The fair value of RSU and PRSU awards is based on the grant date share price. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and RSUs and on an accelerated basis for PRSUs.

In 2016, the Company modified certain stock options and RSU awards. The terms of the stock option modifications included acceleration of vesting and extensions of post-termination exercise periods. The terms of the RSU award modifications included acceleration of vesting. A total of 14 employees were affected by the stock option and RSU modifications and the total incremental compensation cost relating to these modifications was \$0.3 million.

Expected term—The expected term represents the period that the Company’s stock-based awards are expected to be outstanding and is determined using the simplified method (based on the midpoint between the vesting date and the end of the contractual term).

Expected volatility—Because the Company was privately held until its initial public offering in February 2015 and did not have any trading history for its common stock, the Company estimates expected volatility using its own stock price volatility when available as well as the average volatility for comparable publicly traded life sciences companies, including molecular diagnostics companies, over a period equal to the expected term of stock option grants and RSUs. When selecting comparable publicly-traded biopharmaceutical companies, including molecular diagnostics companies, the Company selected companies with comparable characteristics, including enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected life of the stock-based awards. The Company computed historical volatility data using daily closing prices for the selected companies’ shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. The Company estimates expected volatility for ESPP purchases using its own stock price volatility over the expected six-month term ESPP purchase periods.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Dividend yield—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

The fair value of share-based payments for stock options granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model based on the following assumptions:

	Year Ended December 31,		
	2018	2017	2016
Expected term (in years)	6.00	6.03	6.03
Expected volatility	59.58%	72.64%	71.42%
Risk-free interest rate	2.80%	2.01%	1.37%

Stock-based compensation related to stock options granted to non-employees is recognized as the stock options vest. The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option-pricing model based on the following assumptions:

	Year Ended December 31,		
	2018	2017	2016
Expected term (in years)	—	8.41 – 8.83	6.25 – 10.00
Expected volatility	—	69.9 – 78.70%	76.92%
Risk-free interest rate	—	1.83 – 2.04%	1.55 – 2.37%

No stock options granted to non-employees vested during the year ended December 31, 2018.

The fair value of shares purchased pursuant to the ESPP is estimated using the Black-Scholes option pricing model. For the years ended December 31, 2018, 2017 and 2016, the weighted average grant date fair value per share for the ESPP was \$3.26, \$2.51 and \$2.66, respectively and stock-based compensation expense for the ESPP was \$1.4 million, \$1.1 million and \$0.9 million, respectively.

The fair value of the shares purchased pursuant to the ESPP was estimated using the following assumptions:

	Year Ended December 31,		
	2018	2017	2016
Expected term (in years)	0.5	0.5	0.5
Expected volatility	71.66%	52.50%	66.31%
Risk-free interest rate	2.09%	1.23%	0.50%

The following table summarizes stock-based compensation expense for the years ended December 31, 2018, 2017 and 2016, included in the consolidated statements of operations (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cost of revenue	\$ 2,960	\$ 2,093	\$ 1,353
Research and development	7,017	6,158	4,976
Selling and marketing	4,887	3,956	1,709
General and administrative	5,986	7,014	2,661
Total stock-based compensation expense	\$ 20,850	\$ 19,221	\$ 10,699

At December 31, 2018, unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was \$4.5 million, which the Company expects to recognize on a straight-line basis over a weighted-average period of 1.8 years. Unrecognized compensation expense related to RSUs at December 31, 2018, net of estimated forfeitures, was \$22.6 million, which the

12. Income taxes

The Company recorded a benefit for income taxes in the years ended December 31, 2018 and 2017. The Company did not record a provision or benefit for income taxes during the year ended December 31, 2016. The components of net loss before taxes by U.S. and foreign jurisdictions are as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
United States	\$ 132,194	\$ 124,108	\$ 99,793
Foreign	(39)	1,128	463
Total	\$ 132,155	\$ 125,236	\$ 100,256

The components of the provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Current:			
Foreign	62	—	—
Total current benefit for income taxes	62	—	—
Deferred:			
Federal	(2,862)	(1,704)	—
State	—	(152)	—
Total deferred benefit for income taxes	(2,862)	(1,856)	—
Total income tax benefit	\$ (2,800)	\$ (1,856)	\$ —

The following table presents a reconciliation of the tax expense computed at the statutory federal rate and the Company's tax expense for the periods presented:

	Year Ended December 31,		
	2018	2017	2016
U.S. federal taxes at statutory rate	21.0 %	34.0 %	34.0 %
State taxes (net of federal benefit)	5.2 %	3.3 %	1.4 %
Stock-based compensation	(0.7)%	(1.1)%	(1.7)%
Research and development credits	2.7 %	— %	— %
Non-deductible expenses	(0.6)%	— %	0.2 %
Foreign tax differential	— %	(0.3)%	(0.2)%
Other	— %	— %	1.1 %
Change in valuation allowance	(25.5)%	(34.4)%	(34.8)%
Change in deferred—Tax Reform	— %	(39.0)%	— %
Change in valuation allowance—Tax Reform	— %	39.0 %	— %
Total	2.1 %	1.5 %	— %

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	As of December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	\$ 76,972	\$ 70,825
Tax credits	15	15
Revenue recognition differences	47,650	29,819
Accruals and other	7,262	5,544
Gross deferred tax assets	131,899	106,203
Valuation allowance	(121,954)	(95,687)
Total deferred tax assets	9,945	10,516
Deferred tax liabilities:		
Property and equipment	(9,945)	(10,516)
Total deferred tax liabilities	(9,945)	(10,516)
Net deferred tax assets	\$ —	\$ —

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law making significant changes to the Internal Revenue Code. Changes included among other items, a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%. Although the Tax Act was generally effective January 1, 2018, GAAP required recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017. As a result of the lower corporate tax rate enacted as part of the Tax Act, during 2017, the Company recorded a provisional estimate to reduce deferred tax assets by \$48.8 million offset by a corresponding reduction in the valuation allowance resulting in no net impact to the Company's income tax benefit or expense.

On December 22, 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, during 2017, the Company recorded a provisional estimate which resulted in a \$48.8 million reduction in deferred tax assets and in the fourth quarter of 2018, the Company completed its analysis of the impact of the Tax Act and determined that no material adjustments were required to the provisional amounts previously recorded.

The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets. The Company's valuation allowance increased by \$26.3 million, \$2.0 million, and \$33.4 million during the years ended December 31, 2018, 2017, and 2016, respectively.

As of December 31, 2018, the Company had net operating loss carryforwards of approximately \$318.7 million and \$134.3 million available to reduce future taxable income, if any, for Federal and state income tax purposes, respectively. Of the \$318.7 million, \$277.3 million will begin to expire in 2030 while \$41.4 million have no expiration date. The state net operating loss carryforwards will begin to expire in 2030.

As of December 31, 2018, the Company had research and development credit carryforwards of approximately \$9.0 million and \$7.4 million available to reduce its future tax liability, if any, for Federal and state income tax purposes, respectively. The Federal credit carryforwards begin to expire in 2030. California credit carryforwards have no expiration date.

Internal Revenue Code ("IRC") section 382 places a limitation (the "Section 382 limitation" or "annual limitation") on the amount of taxable income that can be offset by net operating loss carryforwards after a change in control (generally greater than 50% change in ownership) of a loss corporation. Similar provisions exist for states. In addition, and as a result of the acquisitions of Good Start Genetics and CombiMatrix in 2017, tax loss carryforwards from acquired entities are also subject to the Section 382 limitation due to the change in control in the acquired entities in the current year.

The Company performed a section 382 analysis for Good Start Genetics and CombiMatrix and concluded that a substantial portion of the acquired operating loss and credit carryovers would expire unused as a result of

annual limitations under IRC sections 382 and 383 in 2017. As a result, the federal and state operating loss and credit carryforwards acquired in connection with the Good Start Genetics and CombiMatrix acquisitions were reduced by the amount of tax attributes estimated to expire during their respective carryforward periods. In addition, as a result of equity issued in connection with its 2017 acquisitions, the Company also performed a section 382 analysis with respect to its legacy operating loss and credit carryforwards. The Company concluded while an ownership change occurred in 2017 as defined under IRC section 382, none of the Company's legacy carryforwards would expire unused solely as a result of annual limitations imposed on the use of the carryforwards under IRC sections 382 and 383.

As of December 31, 2018, the Company had unrecognized tax benefits of \$16.4 million, which primarily relates to research and development credits, none of which would currently affect the Company's effective tax rate if recognized due to the Company's deferred tax assets being fully offset by a valuation allowance. Unrecognized tax benefits are not expected to change in the next 12 months.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year ended December 31,		
	2018	2017	2016
Unrecognized tax benefits, beginning of period	\$ 10,561	\$ 7,791	\$ 11,429
Gross increases—current period tax positions	5,686	2,552	782
Gross increases (decreases)—prior period tax positions	128	218	(4,420)
Unrecognized tax benefits, end of period	\$ 16,375	\$ 10,561	\$ 7,791

The Company's policy is to include penalties and interest expense related to income taxes as a component of tax expense. The Company has not accrued interest and penalties related to the unrecognized tax benefits reflected in the financial statements for the years ended December 31, 2018, 2017 and 2016.

The Company's major tax jurisdictions are the United States and California. All of the Company's tax years will remain open for examination by the Federal and state tax authorities for three and four years, respectively, from the date of utilization of the net operating loss or research and development credit. The Company does not have any tax audits pending.

13. Net loss per share

The following table presents the calculation of basic and diluted net loss per share for the years ended December 31, 2018, 2017 and 2016 (in thousands, except per share data):

	Year ended December 31,		
	2018	2017	2016
Net loss	\$ (129,355)	\$ (123,380)	\$ (100,256)
Shares used in computing net loss per share, basic and diluted	66,747	46,512	33,176
Net loss per share, basic and diluted	\$ (1.94)	\$ (2.65)	\$ (3.02)

The following common stock equivalents have been excluded from diluted net loss per share for the years ended December 31, 2018, 2017 and 2016 because their inclusion would be anti-dilutive (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Shares of common stock subject to outstanding options	3,855	4,115	4,491
Shares of common stock subject to outstanding warrants	611	1,962	—
Shares of common stock subject to outstanding RSUs	4,031	2,387	892
Shares of common stock subject to outstanding PRSUs	—	—	530
Shares of common stock pursuant to ESPP	63	59	55
Shares of common stock underlying Series A convertible preferred stock	3,459	3,459	—
Total shares of common stock equivalents	12,019	11,982	5,968

14. Geographic information

Revenue by country is determined based on the billing address of the customer and is summarized as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
United States	\$ 138,239	\$ 62,446	\$ 20,758
Canada	4,206	3,226	2,526
Rest of world	5,254	2,549	1,764
Total revenue	\$ 147,699	\$ 68,221	\$ 25,048

As of December 31, 2018 and 2017, all long-lived assets were located in the United States.

15. Selected quarterly data (unaudited)

The following table summarizes the Company's quarterly financial information for 2018 and 2017 (in thousands, except per share amounts):

	Three Months Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Revenue	\$ 27,671	\$ 37,306	\$ 37,366	\$ 45,356
Cost of revenue	\$ 18,076	\$ 20,447	\$ 20,441	\$ 21,141
Loss from operations	\$ (36,475)	\$ (30,068)	\$ (30,110)	\$ (25,904)
Net loss ⁽²⁾	\$ (36,120)	\$ (31,671)	\$ (31,723)	\$ (29,841)
Net loss per share, basic and diluted ⁽¹⁾	\$ (0.66)	\$ (0.47)	\$ (0.45)	\$ (0.40)

	Three Months Ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Revenue	\$ 10,338	\$ 14,336	\$ 18,148	\$ 25,399
Cost of revenue	\$ 9,329	\$ 10,490	\$ 13,274	\$ 17,049
Loss from operations	\$ (27,337)	\$ (28,075)	\$ (30,976)	\$ (34,891)
Net loss ⁽²⁾	\$ (26,928)	\$ (28,557)	\$ (27,402)	\$ (40,493)
Net loss per share, basic and diluted ⁽¹⁾	\$ (0.64)	\$ (0.66)	\$ (0.57)	\$ (0.78)

⁽¹⁾ Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of quarterly net loss per share information may not equal annual net loss per share.

(2) Includes \$5.3 million of debt extinguishment costs during the three months ended December 31, 2018. See Note 9, "Commitments and contingencies" for further information.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

ITEM 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer) have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal controls

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation described in Item 9A above that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining internal control over our financial reporting. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework (2013 Framework). Based on the assessment using those criteria, our management concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

ITEM 9B. Other Information.

As of the date of this filing, Patricia E. Dumond has ceased to serve as our Principal Accounting Officer. Shelly D. Guyer, age 58, our Chief Financial Officer since June 2017, has been appointed to serve in the additional position of Principal Accounting Officer. Ms. Guyer served as Chief Financial Officer of Veracyte, Inc., a genomic diagnostics company, from April 2013 to December 2016 and served as Veracyte's Secretary from April 2013 to March 2014. Ms. Guyer has no family relationships with any of our directors or executive officers, and she has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K. Ms. Dumond will continue as an employee of Invitae working on various matters, including direct offering of product lines into the marketplace.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance.

The information required by this item with respect to directors is incorporated by reference from the information under the caption "Election of Directors," contained in our proxy statement to be filed with the Securities and Exchange Commission no later than 120 days from the end of our fiscal year ended December 31, 2018 in connection with the solicitation of proxies for our 2019 Annual Meeting of Stockholders, or the Proxy Statement. Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption "Executive Officers of the Registrant" and is incorporated herein by reference.

There have been no material changes to the procedures by which stockholders may recommend nominees to our Board of Directors.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. This disclosure is contained in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement and is incorporated herein by reference.

Our board of directors has adopted a code of ethics for senior financial officers applicable to our Chief Executive Officer and Chief Financial Officer as well as other key management employees addressing ethical issues. The code of business conduct and the code of ethics are each posted on our website www.invitae.com. The code of business conduct and the code of ethics can only be amended by the approval of a majority of our board of directors. Any waiver to the code of business conduct for an executive officer or director or any waiver of the code of ethics may only be granted by our board of directors or our nominating and corporate governance committee and must be timely disclosed as required by applicable law. We have implemented whistleblower procedures that establish formal protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures will be communicated promptly to our audit committee. Stockholders may request a free copy of our code of business conduct and code of ethics by contacting Invitae Corporation, Attention: Chief Financial Officer, 1400 16th Street, San Francisco, California 94103.

To date, there have been no waivers under our code of business conduct or code of ethics. We intend to disclose future amendments to certain provisions of our code of business conduct or code of ethics or waivers of such codes granted to executive officers and directors on our website at <http://www.invitae.com> within four business days following the date of such amendment or waiver.

Our Board of Directors has appointed an Audit Committee, comprised of Eric Aguiar, Geoffrey S. Crouse and Christine M. Gorjanc. The Board of Directors has determined that each of the members of our Audit Committee qualifies as an Audit Committee Financial Expert under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an "independent director" under the current rules of the New York Stock Exchange and Securities and Exchange Commission rules and regulations.

ITEM 11. Executive Compensation.

The information required by this item is incorporated by reference from the information under the captions "Election of Directors-Director Compensation" and "Executive Compensation" contained in the Proxy Statement.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to the disclosure appearing under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation-Equity Compensation Plan Information" contained in the Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference from the information under the caption "Election of Directors-Certain Relationships and Related Transactions" and "Director Independence" contained in the Proxy Statement.

ITEM 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference from the information under the caption "Ratification of the Appointment of Independent Registered Public Accounting Firm" contained in the Proxy Statement.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules.

- (a) Documents filed as part of this report
1. *Financial Statements*: Reference is made to the Index to Financial Statements of Invitae Corporation included in Item 8 of Part II hereof.
 2. *Financial Statement Schedules*: All schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto.
 3. *Exhibits*: See Item 15(b) below. Each management contract or compensating plan or arrangement required to be filed has been identified.
- (b) Exhibits

Exhibit Number	Description
2.1&@	<u>Stock Purchase Agreement dated as of January 6, 2017 by and among Invitae Corporation, each of the selling shareholders listed on Schedule 1 thereto, and the sellers' agent (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed January 6, 2017).</u>
2.2@	<u>Form of Stock Exchange Agreement dated as of June 11, 2017 by and among Invitae Corporation, each of the selling stockholders listed on Schedule 1 thereto, and the sellers' agent (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed June 13, 2017).</u>
2.3@	<u>Agreement and Plan of Merger and Reorganization, dated as of July 31, 2017, by and among Invitae Corporation, Coronado Merger Sub, Inc. and CombiMatrix Corporation (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
2.4@	<u>Agreement and Plan of Merger, dated as of July 31, 2017, by and among Invitae Corporation, Bueno Merger Sub, Inc., Good Start Genetics, Inc., the Noteholders, the Management Carveout Plan Participants, and OrbiMed Private Investments III, LP as the Holders' Representative (incorporated by reference to Exhibit 2.2 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
2.5	<u>Securities Purchase Agreement, dated as of November 6, 2018, by and among Invitae Corporation and the investors party thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed November 7, 2018).</u>
3.1	<u>Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed February 23, 2015).</u>
3.1.1	<u>Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Invitae Corporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
3.2	<u>Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed February 23, 2015).</u>
4.1	<u>Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
4.2	<u>Registration Rights Agreement, dated as of July 31, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
4.3	<u>Amended and Restated Registration Rights Agreement, dated as of July 31, 2017 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
4.4	<u>Form of Invitae Corporation Series D Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-4 (File No. 333-220447), as amended, filed September 13, 2017).</u>

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4.5 [Form of Invitae Corporation Series F Warrant Offer Agreement \(incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-4 \(File No. 333-220447\), as amended, filed September 13, 2017\).](#)

4.6 [Form of Invitae Corporation Series F Warrant \(incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-4 \(File No. 333-220447\), as amended, filed September 13, 2017\).](#)

Exhibit Number	Description
4.7	<u>Form of Invitae Corporation Series F Warrant Agent Agreement (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-4 (File No. 333-220447), as amended, filed September 13, 2017).</u>
10.1	<u>Form of Indemnification Agreement between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.2#	<u>2010 Stock Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.3#	<u>Form of Notice of Stock Option Grant and Stock Option Agreement—Standard Exercise for awards granted under 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.4#	<u>Form of Notice of Stock Option Grant and Stock Option Agreement—Early Exercise for awards granted under 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.5#	<u>2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.6#	<u>Form of Notice of Stock Option Grant and Non-Qualified Stock Option Agreement for awards granted under the 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.7#	<u>Form of Notice of Restricted Stock Award and Restricted Stock Agreement for awards granted under the 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.8#	<u>Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement for Awards Granted under the 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed August 6, 2015).</u>
10.9#	<u>Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.10	<u>Lease Agreement dated as of September 2, 2015 by and between 1400 16th Street LLC, a Delaware limited liability company, and Invitae Corporation (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed September 4, 2015).</u>
10.11	<u>Loan and Security Agreement dated as of July 17, 2015 between Silicon Valley Bank and Invitae Corporation (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 22, 2015).</u>
10.12&	<u>Loan and Security Agreement dated as of March 15, 2017 between Oxford Capital, LLC and Invitae Corporation (incorporated by reference to Exhibit 10.13 to the Registrant's Amendment No. 2 to Annual Report on Form 10-K for the year ended December 31, 2016).</u>
10.13	<u>First Amendment to Loan and Security Agreement entered into as February 26, 2018 between Oxford Finance LLC and Invitae Corporation together with its subsidiaries PatientCrossroads, Inc., Good Start Genetics, Inc., Ommdom Inc., Combimatrix Corporation and Combimatrix Molecular Diagnostics, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed February 28, 2018).</u>
10.14	<u>Second Amendment to Loan and Security Agreement entered into as of June 29, 2018 between Oxford Finance LLC and Invitae Corporation together with its subsidiaries PatientCrossroads, Inc., Good Start Genetics, Inc., Ommdom Inc., Combimatrix Corporation and Combimatrix Molecular Diagnostics, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed June 29, 2018).</u>

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[Form of Transferable Common Stock between Invitae Corporation and Invitae Corporation \(incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016\).](#)

10.16 [Note Purchase Agreement, dated as of November 6, 2018, by and among Invitae Corporation, the guarantors from time to time party thereto, INN SA LLC, as collateral agent, and the purchasers listed therein or otherwise party thereto from time to time \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed November 7, 2018\).](#)

Exhibit Number	Description
10.17#	Offer Letter, dated May 19, 2017, between Invitae Corporation and Shelly Guyer (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 1, 2017).
10.18	Marketing and Laboratory Services Agreement dated as of September 25, 2017 by and between Invitae Corporation, Good Start Genetics, Inc. and CombiMatrix Molecular Diagnostics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed September 27, 2017).
10.19*	Sales Agreement dated August 9, 2018 between Invitae Corporation and Cowen and Company, LLC.
21.1*	List of Subsidiaries.
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (contained on the signature page to this Form 10-K).
31.1*	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
32.2+	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

Indicates management contract or compensatory plan or arrangement.

* Filed herewith.

@ The schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

+ In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the registrant specifically incorporates it by reference.

& Confidential treatment has been granted with respect to certain portions of this exhibit.

Copies of the above exhibits not contained herein are available to any stockholder, upon payment of a reasonable per page fee, upon written request to: Chief Financial Officer, Invitae Corporation, 1400 16th Street, San Francisco, California 94103.

(c) Financial Statement Schedules: Reference is made to Item 15(a) 2 above.

ITEM 16. Form 10-K Summary.

EXHIBIT 2

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2021

[] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to
Commission File No. 001-36847



Invitae Corporation

(Exact name of the registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

27-1701898
(I.R.S. Employer
Identification No.)

1400 16th Street, San Francisco, California 94103
(Address of principal executive offices, Zip Code)
(415) 374-7782

(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Table with 3 columns: Title of each class, Trading Symbol, Name of exchange on which registered. Row 1: Common Stock, \$0.0001 par value per share, NVTA, New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [X] No []

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [] No [X]

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No []

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (\$232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No []

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [X] Accelerated filer [] Non-accelerated filer [] Smaller reporting company [] Emerging growth company []

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. []

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. [X]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes [] No [X]

As of June 30, 2021, the aggregate market value of common stock held by non-affiliates of the Registrant was approximately \$6.8 billion, based on the closing price of the common stock as reported on The New York Stock Exchange for that date.

The number of shares of the registrant's Common Stock outstanding as of February 25, 2022 was 228,356,928.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III incorporate by reference information from the registrant's proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant's 2022 Annual Meeting of Stockholders.

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SIGNATURES

Forward-Looking Statements

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this report other than statements of historical fact, including statements identified by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect” and similar expressions, are forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our views regarding the future of genetic testing and its role in mainstream medical practice;
- the impact of the COVID-19 pandemic on our business and the actions we have taken or may take in response thereto;
- our mission and strategy for our business, products and technology;
- the implementation of our business model and our success entering new markets;
- the expected benefits from and our ability to integrate our acquisitions;
- our ability to obtain regulatory approvals for our tests;
- the rate and degree of market acceptance of our tests and genetic testing generally;
- our ability to scale our infrastructure and operations in a cost-effective manner;
- the timing of and our ability to introduce improvements to our genetic testing platform and to expand our assays to include additional genes;
- the timing and results of studies with respect to our tests;
- developments and projections relating to our competitors and our industry;
- our competitive strengths;
- the degree to which individuals will share genetic information generally, as well as share any related potential economic opportunities with us;
- our commercial plans, including our sales and marketing expectations as well as our ability to expand internationally;
- our ability to obtain and maintain adequate reimbursement for our tests;
- regulatory developments in the United States and foreign countries;
- our ability to attract and retain key scientific, sales, engineering or management personnel;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- the effects of litigation or investigations on our business;
- our ability to obtain funding for our operations and the growth of our business, including potential acquisitions;
- our financial performance;
- our expectations regarding environmental, social and governance matters;
- the impact of accounting pronouncements and our critical accounting policies, judgments, estimates and assumptions on our financial results;
- our expectations regarding our future revenue, cost of revenue, operating expenses and capital expenditures, and our future capital requirements; and
- the impact of tax laws on our business.

Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Item 1A. of this report. Although we believe that the expectations and assumptions reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statements in this report speak only as of the date of this report. We expressly disclaim any obligation or undertaking to update any forward-looking statements.

In this report, all references to “Invitae,” “we,” “us,” “our,” or “the Company” mean Invitae Corporation.

Invitae and the Invitae logo are trademarks of Invitae Corporation. AMP™, LiquidPlex™, VariantPlex® and FusionPlex®, are the property of ArcherDX, LLC, a wholly owned subsidiary of Invitae Corporation. We also refer to trademarks of other companies and organizations in this report.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties that could affect our ability to successfully implement our business strategy and affect our financial results. You should carefully consider all of the information in this report and, in particular, the following principal risks and all of the other specific factors described in Item 1A. of this report, "Risk Factors," before deciding whether to invest in our company.

- We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.
- Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.
- We have acquired and may continue to acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.
- We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.
- We need to scale our infrastructure in advance of demand for our tests and other products and services, and our failure to generate sufficient demand for our products and services would have a negative impact on our business and our ability to attain profitability.
- We face risks related to health epidemics, including the ongoing COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.
- If third-party payers, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.
- We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the markets in which we operate. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.
- We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.
- The market for patient data software is competitive, and our business will be adversely affected if we are unable to successfully compete.
- Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- If we are not able to continue to generate substantial demand of our tests, our commercial success will be negatively affected.
- If our therapy selection in vitro diagnostic ("IVD") and Personalized Cancer Monitoring ("PCM") products and related services do not perform as expected, we may not realize the expected benefits of our acquisition of ArcherDX.
- The future growth of our distributed products business is partially dependent upon regulatory approval and market acceptance of our IVD products.
- Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.
- If the Food and Drug Administration ("FDA") regulates the tests we currently offer as laboratory-developed tests ("LDTs") as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.
- If we are unable to transition to the new European Union In Vitro Diagnostic Regulation ("IVDR") regulations, we could lose the ability to serve the European market.

- We may not be able to obtain regulatory clearance or approval of our IVD products, or even if approved, such products may not be approved for guideline inclusion, which could adversely affect our ability to realize the intended benefits of our acquisition of ArcherDX.
- One of our competitors has alleged that our Anchored Multiplex PCR, or AMP, chemistry and products using AMP are infringing on its intellectual property, and we may be required to redesign the technology, obtain a license, cease using the AMP chemistry altogether and/or pay significant damages, among other consequences, any of which would have a material adverse effect on our business as well as our financial condition and results of operations, and the intended benefits of our acquisition of ArcherDX.
- We have a large amount of debt, servicing our debt requires a significant amount of cash, and our debt service obligations may prevent us from taking actions that we would otherwise consider to be in our best interests.

PART I

ITEM 1. Business

Overview

Invitae is in the business of delivering genetic testing services, digital health solutions and health data services that support a lifetime of patient care and improved outcomes – from inherited disease diagnoses, to family planning, to proactive health screening to personalized diagnosis, treatment and monitoring of cancer. Testing and other services are delivered via a unique, rapidly expanding platform that serves patients, healthcare providers, biopharma companies and other partners, thereby capturing the broad potential of genetics and helping to expand its use across the healthcare continuum. Invitae applies proprietary design, process automation, robotics and bioinformatics software solutions to expand the use and impact of genetic information and achieve efficiencies in sample processing and complex variant interpretation, allowing medical interpretation at scale. The result is a new and simplified process for obtaining and using affordable, high-quality genetic information to inform critical healthcare decisions. That access and scale also enable genomic information to speed the discovery and development of new personalized medical therapies — all while making clinical genetic testing available to billions of people.

By pioneering new ways of sharing, understanding and applying genetic information, Invitae is transforming the field of genetics and the application of healthcare data from a series of one-time, one-dimensional queries to a lifelong clinical dialogue with our genes using complex analyses and information management to improve medical decisions, optimize health interventions and improve the delivery of healthcare across a lifetime.

Mission and strategy

Invitae's mission is to bring comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people. Our goal is to aggregate a majority of the world's genetic information into a comprehensive network that enables sharing of data among network participants to improve healthcare and clinical outcomes.

We were founded on four core principles:

- Patients should own and control their own genetic information;
- Healthcare professionals are fundamental in ordering and interpreting genetic information;
- Driving down the price of genetic information will increase its clinical and personal utility; and
- Genetic information is more valuable when shared.

Our strategy for long-term growth centers on five key drivers of our business, which we believe work in conjunction to create a flywheel effect extending our leadership position in the new market we are building:



- **Expanding our content offering.** We intend to continue steadily adding additional testing and analysis content to the Invitae platform, ultimately leading to affordable and ongoing access to the molecular information that enables personalized medicine. The breadth and depth of our offering is a core and central contribution to an improved user experience.
- **Creating a unique user experience.** A state-of-the-art interactive platform will enhance our service offering, leverage the uniquely empowering characteristics of online sharing of genetic information and, we believe, enable a superior economic offering to clients. We intend to continue to expend substantial efforts developing, acquiring and implementing technology-driven improvements to our customers' experience. We believe that an enhanced user experience and the resulting benefits to our brand and reputation will help draw customers to us over and above our direct efforts to do so.
- **Driving volume.** We intend to increase our brand equity and visibility through a commitment to precision testing results, excellent service and a variety of marketing and promotional techniques, including scientific publications and presentations, sales, marketing, public relations, social media and web technology vehicles. We believe that rapidly increasing the number of customers using our platform helps us to attract partners.
- **Attracting partners.** As we add more customers to our platform, we believe our business becomes particularly attractive to potential partners that can help the patients in our network further benefit from their genetic information or that provide us access to new customers who may wish to join our network. We believe the cumulative effect of the increased volume brought by these strategic components will allow us to lower the cost of our service and expand patient access globally.
- **Lowering the cost and price of genetic information.** Our goal is to provide customers with a broad menu of genetic content at a reasonable price and rapid turn-around times in order to grow volume and, in turn, achieve greater economies of scale. As our customers and our business benefit from further cost savings, we expect that those cost savings will allow us to deliver still more comprehensive information at decreasing prices and further improve the customer experience, allowing us to reap the cumulative benefits from all of the efforts outlined above.

We seek to differentiate our service in the market by establishing an exceptional experience for our customers. To that end, we believe that elevating the needs of the customer over those of our other stakeholders is essential to our success. Thus, in our decision-making processes, we strive to prioritize, in order:

- The needs of our customers;
- Motivating our employees to serve our customers; and
- Our long-term stockholder value.

We are certain that focusing on customers as our top priority rather than short-term financial goals is the best way to build and operate an organization for maximum long-term value creation.

Business overview

We are focused on making comprehensive, high-quality genetic information more accessible by lowering the cost of genetic testing, by utilizing a testing delivery platform that is accessible to patients throughout their lives, by enabling a growing network of partners to increase the utility of genetic information across the healthcare continuum, and, ultimately, by managing that information on behalf of our customers, enabling improved health and the advancement of molecular medicine around the globe.

As our market share grows, we expect that our business will grow in three stages:

- 1) **Genetic testing:** making genetic testing more affordable and more accessible with fast turnaround time. We believe that there is a significant market opportunity for high-volume, low-cost genetic testing that allows us to serve a large number of customers. We launched our first commercial offering in November 2013 with an offering of approximately 200 genes, growing the test menu over time to include more than 20,000 genes to help diagnose disease, inform family planning, and serve healthy individuals. In 2021, we processed billable volume of approximately 1,169,000 units and generated revenue of \$460.4 million reflecting an approximate 77% and 65% increase over 2020 billable volume and revenue, respectively.

- 2) **Genome network:** sharing genetic information on a global scale to advance science and medicine. We are focusing our efforts on partnering with patients, family members, healthcare professionals, payers, industry professionals, researchers, and clinical trial sponsors to advance the development of our genome network. Our goal is to enable and build a network through which individuals and organizations can access, aggregate, and customize genetic information in order to participate in research, clinical trials, treatment planning, or other related purposes that may benefit the individual and/or their clinician. Individuals can also share information if they feel it will benefit them or will contribute more broadly to furthering knowledge about their conditions.

In addition to investing in informatics solutions and infrastructure to support network development, we have been expanding our partnerships, which now number more than 100 of the world's leading biopharmaceutical companies supporting improved patient diagnosis, clinical trial recruitment and other research-related initiatives. Our biopharmaceutical industry partnerships are complemented by partnerships with leading health systems, executive health programs and leading research institutions, including The Christ Hospital Health Network, the Cleveland Clinic, the Geisinger Health System, the Mayo Clinic, Memorial Sloan Kettering Cancer Center, MedCan, and Stanford Health Care, among others.

We partner with global biopharmaceutical companies such as AstraZeneca AB (Publ), Illumina and Merck KGaA, Darmstadt, Germany, through collaboration agreements to bring new treatment options for patients to market faster by enabling clinical research and trials.

- 3) **Genome management:** building a secure and trusted genome management infrastructure. By generating and storing large amounts of individualized genetic information for every patient sample and enabling the analysis of that cumulative data for broad health research applications, we believe we can create value for all the constituents of our testing platform and partner network. Broad access to centralized, standardized genomic data can benefit patients and their families with information that will improve therapy and outcomes, while it is also expected to aid in the compression of drug development timelines and the greater application of fact-based healthcare decisions throughout life.

Competition

Our competitors include companies that offer molecular genetic testing and consulting services, including specialty and reference laboratories that offer traditional single- and multi-gene tests and biopharmaceutical companies. Principal competitors include companies such as Ambry Genetics, a subsidiary of Konica Minolta Inc.; Athena Diagnostics and Blueprint Genetics, subsidiaries of Quest Diagnostics Incorporated; Baylor-Miraca Genetics Laboratories; Caris Life Sciences, Inc.; Centogene AG; Color Genomics, Inc.; Connective Tissue Gene Test LLC, a subsidiary of Health Network Laboratories, L.P.; Cooper Surgical, Inc.; Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Foundation Medicine, a subsidiary of Roche Holding AG; Fulgent Genetics, Inc.; Guardant Health, Inc.; Integrated Genetics, Sequenom Inc., Correlagen Diagnostics, Inc., and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings; Myriad Genetics, Inc.; Natera, Inc.; Perkin Elmer, Inc.; and Sema4 Genomics; as well as other commercial and academic labs.

In addition, there are a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness, including Illumina, Inc. which is also one of our suppliers. In addition to the companies that currently offer traditional genetic testing services and research centers, other established and emerging healthcare, information technology and service companies may commercialize competitive products including informatics, analysis, integrated genetic tools and services for health and wellness.

We believe the principal competitive factors in our market are:

- breadth and depth of content;
- quality;
- reliability;
- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;

- convenience of testing;
- brand recognition of test provider;
- additional value-added services and informatics tools;
- client service; and
- quality of website content.

We believe that we compare favorably with our competitors on the basis of these factors. However, certain competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration in certain testing categories, substantially greater financial, technological and research and development resources, selling and marketing capabilities, and/or more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests, or sell their tests at prices designed to win significant levels of market share. We may compete less effectively against these organizations in some areas of testing.

Regulation

Reimbursement

Under the Protecting Access to Medicare Act of 2014 (as amended), or PAMA, and its implementing regulations, laboratories that realize at least \$12,500 in Medicare Clinical Laboratory Fee Schedule, or CLFS, revenues during the six month reporting period and that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule must report, beginning in 2017, and then in 2023 and every three years thereafter (or annually for “advanced diagnostic laboratory tests”), private payer payment rates and volumes for their tests. We have not sought advanced diagnostic laboratory test status for our tests and therefore believe we are required to report private payer rates for our tests on an every three years basis starting next in 2023. Centers for Medicare & Medicaid Services, or CMS, uses the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil money penalties.

Since January 1, 2018, Medicare payments for clinical diagnostic laboratory tests have been paid based upon these reported private payer rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the cross-walk or gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test.

Where applicable, reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020. Rates were held at 2020 levels during 2021 and will continue to be held at such levels in 2022, and then, where applicable based upon median private payer rates reported in 2017 or 2023, reduced by up to 15% per test per year in each of 2023 through 2025 (with a second round of private payer rate reporting in 2023 to establish rates for 2024 through 2026).

PAMA codified Medicare coverage rules for laboratory tests by requiring any local coverage determination to be made following the local coverage determination process. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory-specific Medicare Administrative Contractors, or MACs. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate. It is unclear whether CMS will proceed with contractor consolidation under this authorization.

PAMA also authorized the adoption of new, temporary billing codes and/or unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The American Medical Association has created a new section of billing codes, Proprietary Laboratory Analyses, or PLAs, to facilitate implementation of this section of PAMA. These codes may apply to one or more of our tests if we apply for PLA coding.

CMS maintains a national coverage determination, or NCD, for next generation sequencing, or NGS, tests for somatic (acquired) and germline (inherited) cancer testing. For somatic cancer testing, the NCD establishes full coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays that report results using report templates that specify treatment options when offered for their FDA-approved or FDA-cleared use(s), ordered by the patient’s treating physician for Medicare beneficiaries with advanced cancer (recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer) who have not have previously been tested with the same test using

NGS for the same cancer genetic content, and have decided to seek further cancer treatment (e.g., therapeutic chemotherapy.) The NCD also gives MACs the authority to establish local coverage for NGS-based somatic cancer assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It appears that NGS-based somatic cancer tests provided for patients with cancer that do not meet the above-referenced criteria - e.g., patients with earlier stage cancers - are currently nationally non-covered under the NCD.

The NCD also establishes full coverage for FDA-approved or FDA-cleared NGS-based germline tests that report results using report templates that specify treatment options when ordered by the patient's treating physician for patients with ovarian or breast cancer, a clinical indication for germline testing for hereditary breast or ovarian cancer, and a risk factor for germline breast or ovarian cancer, provided the patient has not previously been tested with the same germline test using NGS for the same germline genetic content. The NCD also gives MACs the authority to establish local coverage for NGS-based germline tests for ovarian or breast cancer that are not FDA-approved or FDA-cleared, as well as for NGS-based tests for any other cancer diagnosis (regardless of the test's FDA regulatory status) when offered to patients meeting the above-referenced criteria for germline testing. Since we already have local coverage for our germline tests for ovarian and breast cancer, we believe that the NCD will not have a material impact on which of our tests will be reimbursable by CMS for Medicare patients.

Clinical Laboratory Improvement Amendments of 1988, or CLIA

Our clinical reference laboratories in California, Colorado and New Jersey are required to hold certain federal certificates to conduct our business. Under CLIA, we are required to hold certificates applicable to the type of laboratory examinations we perform and to comply with standards covering personnel, facilities administration, inspections, quality control, quality assurance and proficiency testing.

We have current certifications under CLIA to perform testing at our laboratory locations in San Francisco and Irvine, California, Golden, Colorado, and Iselin, New Jersey. To renew our CLIA certifications, we are subject to survey and inspection every two years to assess compliance with program standards. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

If our clinical reference laboratories are out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificates, as well as directed plan of correction, state on-site monitoring, significant civil money penalties, civil injunctive suit or criminal penalties. We must maintain CLIA compliance and certifications to be eligible to bill for diagnostic services provided to Medicare and Medicaid beneficiaries. If we were to be found out of compliance with CLIA requirements and subjected to sanction, our business could be harmed.

State laboratory licensure requirements

We are required to maintain in-state licenses to conduct testing in California, New Jersey and Washington. California, New Jersey and Washington laws establish standards for day-to-day operations of our laboratories in San Francisco and Irvine, Iselin and Seattle, respectively. Such laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratories. If our clinical reference laboratories are out of compliance with applicable standards, the appropriate state agency may suspend, restrict or revoke our licenses to operate our clinical reference laboratories, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business. We maintain current licenses in good standing. However, we cannot provide assurance that state regulators will at all times in the future find us to be in compliance with all such laws.

Several states require the licensure of out-of-state laboratories that accept specimens from those states. Our California laboratories hold the required out-of-state laboratory licenses for Maryland, New York, Pennsylvania, and Rhode Island. Our Seattle and Iselin laboratories hold the required out-of-state laboratory licenses in California, Maryland, New York, Pennsylvania, and Rhode Island. Our laboratory in Golden, Colorado holds the required out-of-state laboratory licenses for California, Maryland, Pennsylvania and Rhode Island (but not New York).

In addition to having laboratory licenses in New York, our clinical reference laboratories are also required to obtain approval on a test-specific basis for the tests they run as LDTs by the New York State Department of Health, or NYDOH, before specific testing is performed on samples from New York.

Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of human blood or saliva necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States.

Federal oversight of laboratory developed tests

We provide many of our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by CLIA and state law, respectively).

Historically, the U.S. Food and Drug Administration, or FDA, has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality system regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. For example, in 2014, the FDA issued two draft guidance documents that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. These documents have not been finalized to date.

Subsequently, in August 2020, the U.S. Department of Health and Human Services – the parent agency for FDA – announced that the FDA “will not require premarket review of LDTs absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances.” In November 2021, the Biden Administration rescinded this policy.

At this time, it is unclear when, or if, the FDA will finalize its plans to end enforcement discretion (e.g., via notice and comment rulemaking or otherwise), and even then, the new regulatory requirements are expected to be phased-in over time. Nevertheless, the FDA may attempt to regulate certain LDTs on a case-by-case basis at any time.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in the current and previous Congresses, and we expect that new legislative proposals will be introduced from time-to-time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time.

If the FDA ultimately regulates certain LDTs, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition, and results of operations.

Notwithstanding the FDA's current position with respect to oversight of our LDTs, we may voluntarily decide to pursue FDA pre-market review for our current LDTs and/or LDTs we may offer in the future if we determine that doing so would be appropriate from a strategic perspective – e.g., if CMS indicated that it no longer intended to cover tests offered as LDTs.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

In addition, in November 2013, the FDA issued final guidance regarding the distribution of products labeled for research use only. Certain of the reagents and other products we use in our tests are labeled as research use only products. Certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

Medical device regulatory framework

Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act, or FDCA, the FDA has jurisdiction over medical devices, which are defined to include, among other things, in vitro diagnostics, or IVDs. The FDA regulates the research, design, development, pre-clinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Specifically, for the test we offer that FDA currently regulates as a device, and if the FDA begins to actively regulate LDTs, then for those tests as well, each new or significantly modified test we seek to commercially distribute in the United States could require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a premarket approval, or PMA, application, unless an exemption applies. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Device classification

Under the FDCA, medical devices are classified into one of three classes (Class I, Class II or Class III) depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to General Controls for Medical Devices, which require compliance with the applicable portions of the FDA's Quality System Regulation, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. While some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below, most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These Special Controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review by the FDA. Premarket review by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk, such as life-supporting, life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent to a legally-marketed predicate device. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The 510(k) clearance process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics, but the information submitted demonstrates that the device is as safe and effective and does not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) premarket notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter,

clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including data from samples collected in a clinical setting, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not “substantially equivalent” to a predicate device, or if the device is automatically classified into Class III because there is no available predicate device, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the De Novo classification process. The De Novo classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents moderate or low risk. De Novo classification may also be available after receipt of a “not substantially equivalent” letter following submission of a 510(k) to FDA.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer’s determination. Many minor modifications are accomplished by an internal letter-to-file in which the manufacturer documents its reasoning for why a change does not require premarket submission to the FDA. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer’s determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

The PMA approval process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant’s response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee’s recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA’s satisfaction;
- the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA clearance or approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA’s evaluation of a PMA application or manufacturing facility is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several

months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. New PMA applications or PMA supplements may also be required for modifications to any approved diagnostic tests, including modifications to manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

The investigational device process

In the United States, absent certain exceptions, human clinical trials intended to support medical device clearance or approval require an investigational device exemption, or IDE, application. Investigations that meet certain requirements – i.e., involve tests that are labeled investigational use only (IUO), are noninvasive, do not require an invasive sampling procedure that presents significant risk, do not by design or intention introduce energy into a subject, and are not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established product or procedure — are exempt from the IDE requirement. Some types of studies deemed to present “non-significant risk” are deemed to have an approved IDE — without affirmative submission of an IDE application to the FDA — once certain requirements are addressed and Institutional Review Board, or IRB, approval is obtained. If the device presents a “significant risk” to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials.

Where applicable, the IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Such clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA for any clinical trials subject to FDA oversight. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a 510(k) premarket notification, for numerous reasons.

The Breakthrough Devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, provided the device also represents breakthrough technology, is one for which no approved or cleared treatment exists, offers significant advantages over existing approved or cleared alternatives, or is one whose availability is in the best interest of patients. All submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as

needed. Although Breakthrough Device designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory clearance or approval for such product.

Research use only, or RUO

In the United States, products labeled and sold for research use only, and not for the diagnosis or treatment of disease, are sold to a variety of parties, including biopharmaceutical companies, academic institutions and molecular labs. Because such products are not intended for use in clinical practice in diagnostics, and the products cannot include clinical or diagnostic claims, they are exempt from many regulatory requirements otherwise applicable to medical devices. In particular, while the FDA regulations require that RUO products be labeled, "For Research Use Only. Not for use in diagnostic procedures," the regulations do not otherwise subject such products to the FDA's pre- and post-market controls for medical devices.

A significant change in the laws governing RUO products or how they are enforced may require a change to our RUO products business model in order to maintain compliance. For instance, in November 2013 the FDA issued a guidance document entitled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only", or the RUO Guidance, which highlights the FDA's interpretation that distribution of RUO products with any labeling, advertising or promotion that suggests that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as a laboratory developed test is in conflict with RUO status. The RUO Guidance further articulates the FDA's position that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, conflicts with RUO status. If we engage in any activities that the FDA deems to be in conflict with the RUO labeling on the products that we sell, we may be subject to immediate, severe and broad FDA enforcement action that would adversely affect our ability to continue operations selling these products. Accordingly, if the FDA finds that we are distributing RUO products in a manner that is inconsistent with its regulations or guidance, we may be forced to stop distribution of our RUO products until we are in compliance, which would reduce our revenues, increase our costs and adversely affect our business, prospects, results of operations and financial condition. In addition, if the FDA ends enforcement discretion for LDTs, it may negatively impact the LDT market and thereby reduce demand for RUO products. If the FDA requires marketing authorization of our RUO products in the future, there can be no assurance that the FDA will ultimately grant any clearance or approval we request in a timely manner, or at all.

Post-market regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- Quality System Requirements ("QSR"), which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;

- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- requesting or requiring recalls, withdrawals, or administrative detention or seizure of our products;
- imposing operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

HIPAA and state privacy, security and breach notification laws

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, the U.S. Department of Health and Human Services issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and requirements for protecting the privacy and security of protected health information, or PHI, used or disclosed by covered entities, including most health care providers and their respective business associates, as well as the business associates' subcontractors. We are required to comply with the provisions of HIPAA and HITECH and the regulations implemented thereunder setting forth standards for the privacy of PHI; security standards for the protection of electronic PHI; breach notification requirements; and standards for electronic transactions, which establish standards for common healthcare transactions.

The HIPAA privacy regulations establish requirements and restrictions for the use and disclosure of PHI by covered entities as well as business associates, which are persons or entities that perform certain functions for or on behalf of a covered entity that involve the creation, receipt, maintenance, or transmittal of PHI. Business associates are defined to include a subcontractor to whom a business associate delegates a function, activity, or service, other than in the capacity of the business associate's workforce. As a general rule, a covered entity or business associate may not use or disclose PHI except as permitted or required under the privacy regulations. The privacy regulations also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity or business associate, including the right to access and amend certain records containing his or her PHI, request restrictions on the use or disclosure of his or her PHI, and request an accounting of disclosures of his or her PHI.

Covered entities and business associates also must comply with the HIPAA security regulations, which establish requirements for safeguarding the confidentiality, integrity, and availability of PHI that is electronically transmitted or electronically stored. The HIPAA security regulations give covered entities and business associates flexibility in complying with certain of the standards and implementation specifications under the regulations.

However, the requirements are extensive and include implementing workforce training, implementing policies and procedures to comply with the HIPAA security regulations, and conducting an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic PHI maintained by the covered entity or business associate.

In addition, covered entities and business associates must comply with certain breach notification requirements. In particular, a covered entity must notify any individual whose unsecured PHI is breached according to the specifications set forth in the HITECH breach notification rule. A covered entity must also notify the Secretary of the U.S. Department of Health and Human Services and, under certain circumstances, the media of a breach of unsecured PHI. A business associate must notify the relevant covered entity of any breach of unsecured PHI.

There are significant civil and criminal penalties that may be imposed on us as a covered entity or business associate for violating HIPAA. A covered entity or business associate may also be liable for civil money penalties for a violation that is based on an act or omission of any of its agents as determined according to the federal common law of agency, which may include a business associate or subcontractor business associates. Complying with HIPAA and HITECH requires significant resources, and we may be restricted in our ability to perform certain activities that involve the collection, use, or disclosure of PHI due to the limitations set forth in the HIPAA privacy regulations. Additionally, to the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

The HIPAA and HITECH privacy, security, and breach notification regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or insofar as such state laws apply to personal information that is broader in scope than PHI as defined under HIPAA. Massachusetts, for example, has a state law that protects the privacy and security of personal information of Massachusetts residents. In addition, every U.S. state has a data breach notification law that requires entities to report certain security breaches to affected consumers and, in some instances, state regulators and consumer reporting agencies. Many states also have laws or regulations that specifically apply to genetic testing and genetic information and are more stringent than the standards under HIPAA. These state genetic information privacy laws include specific informed consent requirements for the conduct of genetic testing and restrict the collection, use, disclosure, or retention of genetic information. A number of states, including California and Florida, have recently enacted new or amended genetic privacy laws. While many of these new genetic privacy laws include exceptions for PHI and for covered entities and business associates to the extent they process genetic information in the same manner as PHI, not all such laws are limited in this manner, and the enactment of these laws may generally bring enhanced scrutiny of companies like us that generate and maintain genetic information. Failure to comply with applicable state laws that impose privacy, security, or breach notification requirements for genetic or other personal information could result in significant civil or criminal penalties, administrative actions, or private causes of action by patients, and adversely affect our business, results of operations and reputation.

Federal and state consumer protection laws

The Federal Trade Commission, or FTC, is an independent U.S. law enforcement agency charged with protecting consumers and enhancing competition across broad sectors of the economy. The FTC has indicated that, in 2022, it will be considering new data privacy regulations, which, if adopted, could impact our operations if they impose substantial new obligations or restrictions with respect to our data collection and processing activities. The FTC's primary legal authority with respect to data privacy and security comes from Section 5 of the FTC Act, which prohibits unfair or deceptive acts or practices in the marketplace. The FTC uses this broad authority to police data privacy and security, using its powers to investigate and bring lawsuits. Where appropriate, the FTC can seek a variety of remedies, such as but not limited to requiring the implementation of comprehensive privacy and security programs, biennial assessments by independent experts, monetary redress to consumers, and provision of robust notice and choice mechanisms to consumers. In addition to its enforcement mechanisms, the FTC uses a variety of tools to protect consumers' privacy and personal information, including pursuing enforcement actions to stop violations of law, conducting studies and issuing reports, hosting public workshops, developing educational materials, and testifying before the U.S. Congress on issues that affect consumer privacy.

The vast majority of data privacy cases brought by the FTC fall under the "deceptive" acts prong of Section 5. These cases often involve a failure on the part of a company to adhere to its own privacy and data protection principles set forth in its policies. To avoid Section 5 violations, the FTC encourages companies to build privacy protections and safeguards into relevant portions of their business, and to consider privacy and data protection as the company grows and evolves. In addition, privacy notices should clearly and accurately disclose the type(s) of

personal information the company collects, how the company uses and shares that information, and the security measures used by the company to protect that information.

In recent years, the FTC's enforcement under Section 5 related to data security has included alleged violations of the "unfairness" prong. Many of these cases have alleged that companies were unfair to consumers because they failed to take reasonable and necessary measures to protect consumer data. The FTC has not provided bright line rules defining what constitutes "reasonable and necessary measures" for implementing a cybersecurity program, but it has provided guidance, tips and advice for companies. The FTC has also published past complaints and consent orders, which it urges companies use as guidance to help avoid an FTC enforcement action, even if a data breach or loss occurs.

In addition to the FTC Act, most U.S. states have unfair and deceptive acts and practices statutes, known as UDAP statutes, that substantially mirror the FTC Act and have been applied in the privacy and data security context. These UDAP statutes vary in substance and strength from state to state. Many have broad prohibitions against unfair and deceptive acts and practices. These statutes generally allow for private rights of action and are enforced by the states' Attorneys General.

California Consumer Privacy Act and Copy Cat Legislation

The California Consumer Privacy Act, or CCPA, is a comprehensive consumer privacy law that took effect on January 1, 2020, and regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of consumers who reside in California. Among other things, the CCPA confers to California consumers the right to: receive notice information collection and use practices; access, delete, or transfer personal information; and opt out of the "sale" of their personal information, which the CCPA defines broadly as any disclosure of personal information to a third party in exchange for monetary or other valuable consideration. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure. The CCPA provides partial exemptions for employee and business-to-business information that are set to expire on January 1, 2023.

The CCPA does not apply to personal information that is PHI under HIPAA. The CCPA also does not apply to a HIPAA-regulated entity to the extent that the entity maintains patient information in the same manner as PHI. In addition, de-identified data as defined under HIPAA is also exempt from the CCPA. Accordingly, we do not have CCPA compliance obligations with respect to most genetic testing and patient information we collect and process. However, we are required to comply with the CCPA insofar as we collect other categories of California consumers' personal information.

The California Attorney General has authority to enforce the CCPA and its implementing regulations against covered businesses. The CCPA provides for civil penalties for violations, as well as private right of action for certain data breaches.

On November 3, 2020, California passed the California Privacy Rights Act, or CPRA, through a ballot initiative. Under the CPRA, a new California Privacy Protection Agency has been created to enforce the CPRA. Among other things, the CPRA will create a new category of "sensitive personal information" and offer consumers the right to limit processing of such information, impose purpose limitation, data minimization, data retention, and security compliance obligations on regulated businesses, and add or modify the rights available to consumers, including by providing a right to correct the information a business holds about them. The CPRA's amendments to the CCPA will take effect on January 1, 2023, and will generally apply to personal information collected by businesses on or after January 1, 2022. CPRA enforcement will begin on July 1, 2023.

On March 2, 2021, Virginia's Governor signed into law the Virginia Consumer Data Protection Act (VCDPA), which will take effect on January 1, 2023. On July 7, 2021, Colorado's Governor signed into law Colorado's Consumer Privacy Act (CPA), which will take effect on July 1, 2023. Like the CPRA, both the VCDPA and the CPA regulate how certain businesses collect, use and disclose the personal information of consumers in either Virginia or Colorado. Both the VCDPA and the CPA provide for substantially the same rights to Virginia and Colorado residents, respectively, as the CPRA does for California residents. Unlike the CPRA, however, both the VCDPA and the CPA permanently exclude information collected from employees or business-to-business contacts. In addition, the VCDPA and CPA will require that companies obtain consent from consumers in Virginia and Colorado before their "sensitive personal information" is collected or processed. The VCDPA and the CPA also allow consumers to opt-out of the use of their information for specific purposes, such as targeted marketing. Both the VCDPA and the CPA do not apply to PHI under HIPAA and both laws also generally exempt HIPAA-regulated entities from their reach. Both the VCDPA and the CPA are enforced by their respective state's Attorney Generals, and neither includes a private right of action.

Dozens of other states in the United States are currently considering similar consumer data privacy laws, which could impact our operations if enacted.

Privacy and data protection laws

There are a growing number of jurisdictions around the globe that have privacy and data protection laws that may apply to Invitae as it enters or expands its business in jurisdictions outside of the United States. These laws are typically triggered by a company's establishment or physical location in the jurisdiction, data processing activities that take place in the jurisdiction, and/or the processing of personal information about individuals located in that jurisdiction. Certain international privacy and data protection laws, such as those in the European Union (EU), are more restrictive and prescriptive than those in the U.S., while other jurisdictions may have laws less restrictive or prescriptive than those in the U.S. Enforcement of these laws varies from jurisdiction to jurisdiction, with a variety of consequences, including civil or criminal penalties, litigation, private rights of action or damage to our reputation.

Europe

The EU's General Data Protection Regulation, or GDPR, took effect on May 25, 2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. The GDPR imposes strict requirements on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, which includes sensitive information such as health and genetic information of data subjects. The GDPR also grants individuals various rights in relation to their personal data, including the rights of access, rectification, objection to certain processing and deletion. The GDPR provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, may result in significant administrative fines issued by EU regulators. Maximum penalties for violations of the EU GDPR are capped at 20 million euros or 4% of an organization's annual global revenue, whichever is greater.

Australia

Australia's federal Privacy Act 1988, or the Privacy Act, and the 13 Australian Privacy Principles, or the APPs, contained in the Privacy Act, apply to government agencies and private sector organizations with annual turnover exceeding AU \$3 million. The Privacy Act extends to all of Australia's external territories, but also applies to an act done, or practice engaged in, or outside Australia (and Australia's external territories) by an organization, or small business operator, that has a link to Australia, such as a continued presence, partnership, incorporation, central management and control, or citizenship in Australia. An organization may also have a link to Australia if the organization conducts business in Australia and collects or stores personal information in Australia. The Privacy Act applies to any collection, holding, use or disclosure of personal information by a regulated entity, with enhanced protections for sensitive information such as genetic information. The Privacy Act prescribes certain rights for individuals, including rights to know why the information is collected, how it is used, and to whom it is disclosed, the right of the individual not to identify themselves in certain circumstances, the right of access, the right to stop receiving unwanted direct marketing, the right to correct information, and the right to make a complaint. Australia's Privacy Commissioner enforces the Privacy Act and any acts that may violate an individual's privacy. The Privacy Commissioner can levy significant fines on individuals and corporations that violate the Privacy Act.

Canada

Canada has several federal, provincial and territorial privacy statutes that govern the protection of personal information. The Personal Information Protection and Electronic Documents Act 2000, or PIPEDA, applies to the collection, use, and disclosure of personal information in the course of commercial activities in Canada. Although PIPEDA is silent with respect to its extraterritorial application, the Federal Court of Canada has concluded that PIPEDA applies to businesses established in other jurisdictions if there is a "real and substantial connection" between the organization's activities and Canada. PIPEDA and provincial data protection laws require specific notices regarding openness and transparency and require regulated organizations to obtain consent in order to process such information. Canadian individuals enjoy rights or access and to correct inaccuracies. Violations of Canadian data protection laws can result in significant fines. Canada is evaluating replacing or substantially amending PIPEDA so as to make it similar to the GDPR. Such changes to PIPEDA could impact our operations if enacted.

India

The Indian Constitution has been interpreted by India's highest court to include a fundamental right to privacy. In addition, the Information Technology Act 2000, as amended, or the IT Act, is the primary national law regulating the collection and use of personal information that is sensitive. The IT Act applies to corporations and other "body corporates" that possess, maintain, or otherwise process personal information, including body corporates that act on behalf of other body corporates. Certain provisions of the IT Act provide liability for negligent handling of personal information. For example, the IT Act provides that any corporation or other body corporate that handles sensitive personal data is liable to pay damages for any loss caused by its negligence in implementing and maintaining reasonable security practices and procedures.

In addition, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules 2011, or the Data Privacy Rules, issued under the IT Act regulate the use of personal information and sensitive personal data. The Data Privacy Rules mandate that businesses have a privacy policy, obtain consent when collecting or transferring personal information, and inform the data subject about any recipients of that data. The IT Act includes a private right of action for individuals, and authorizes criminal punishment (with a fine, three years in prison, or both) for disclosing personal information without the consent of the data subject or in breach of any relevant contract.

India's parliament is currently evaluating a new data privacy bill that would bear many similarities with GDPR, but that would also contain certain additional requirements including, for example, possible data localization requirements. If enacted, India's new law could impact our operations.

Israel

Israel's data protection regime is governed primarily by the Protection of Privacy Law and the regulations promulgated under it, or the PPL, and the guidelines of the Israeli regulator, the Privacy Protection Authority, or the PPA. The PPL applies to: (1) database owners, database holders, and database managers based in Israel; and (2) data processing operations that take place in Israel, regardless of whether the individuals about whom the data relates are residents or citizens of Israel. The PPL could also be interpreted to apply to non-Israeli database owners, database holders, or database managers that process personal information about Israeli residents or citizens when such processing takes place outside of Israel. Various regulations promulgated under the PPL by the PPA set out rules and procedures for data security, data retention, data subject rights, and cross border transfers of data. These regulations also do not clearly state their jurisdictional scope, such that there is a risk they could be interpreted as applying to foreign-based entities that process data about Israeli citizens.

The PPA is required to maintain a registry of databases and is empowered to supervise compliance with and investigate alleged violations of the PPL and related regulations. The PPA may impose administrative fines for violations of the PPL and related regulations, and willful violations may result in criminal liability and up to five years in prison. A breach of privacy is also actionable, and an individual claimant may obtain monetary compensation or injunctive relief. A court may award statutory damages without proof of damages for breach of privacy rights. If the breach was intentional, the damages may be doubled. The PPL also specifies that an act or omission in breach of certain of its provisions, such as failure to ensure data security, may give rise to a tort claim.

Japan

Japan's primary data protection law, the Act on the Protection of Personal Information was amended in 2020 to include GDPR-like requirements, including additional transparency requirements, data transfer obligations, enhanced data breach notification requirements, additional data subject rights and stronger penalties for violations, including significant fines. The amendment clarifies that its provisions, obligations and penalties apply to entities outside of Japan that supply goods or services in Japan and handle personal information from an individual in Japan. These amendments will go into effect on April 1, 2022.

Information blocking prohibition

On May 1, 2020, the Office of the National Coordinator for Health Information Technology promulgated final regulations under the authority of the 21st Century Cures Act to impose new conditions to obtain and maintain certification of certified health information technology and prohibit certain covered actors, including developers of certified health information technology, health information networks / health information exchanges, and health care providers (including laboratories), from engaging in activities that are likely to interfere with the access, exchange, or use of electronic health information (information blocking). The final regulations further defined exceptions for activities that are permissible, even though they may have the effect of interfering with the access, exchange, or use

of electronic health information. The information blocking regulation effective date was April 5, 2021. Under the 21st Century Cures Act, health care providers that violate the information blocking prohibition will be subject to appropriate disincentives, which the U.S. Department of Health and Human Services has yet to establish through required rulemaking. Developers of certified information technology and health information networks / health information exchanges, however, may be subject to civil monetary penalties of up to just over \$1 million (as adjusted for inflation) per violation. If the government were to conclude that we met the definition of a health information network or health information exchange, we could be potentially subject to such penalties. However, the U.S. Department of Health and Human Services Office of Inspector General has the authority to impose such penalties and on April 24, 2020 published a proposed rule to codify new authority in regulation, which the agency proposed would be effective 60 days after it issues a final rule, but in no event before November 2, 2020. The U.S. Department of Health and Human Services Office of Inspector General has not yet issued a final rule.

Federal, state and foreign fraud and abuse laws

In the United States, there are various fraud and abuse laws with which we must comply, and we are potentially subject to regulation by various federal, state and local authorities, including CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, and individual U.S. Attorney offices within the Department of Justice, and state and local governments. We also may be subject to foreign fraud and abuse laws.

In the United States, the federal Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering of any good, facility, service or item for which payment may be made in whole or in part by a federal healthcare program. Many courts have held that the Anti-Kickback Statute may be violated if any one purpose of the remuneration is to induce or reward patient referrals or other federal healthcare program business, regardless of whether there are other legitimate purposes for the arrangement. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, consulting fees, waivers of co-payments, ownership interests, and providing anything at less than its fair market value. The Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry. The Anti-Kickback Statute includes several statutory exceptions, and the U.S. Department of Health and Human Services has issued a series of regulatory "safe harbors." These exceptions and safe harbor regulations set forth certain requirements for various types of arrangements, which, if met, will protect the arrangement from potential liability under the Anti-Kickback Statute. Although full compliance with the statutory exceptions or regulatory safe harbors ensures against liability under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific statutory exception or regulatory safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. Penalties for violations of the Anti-Kickback Statute are severe, and include imprisonment, criminal fines, civil money penalties, and exclusion from participation in federal healthcare programs. Many states also have anti-kickback statutes, some of which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

There are also federal laws related to healthcare fraud and false statements, among others, that apply to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payer programs such as the Medicare and Medicaid programs. The false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payer programs.

Another development affecting the healthcare industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payer program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by presenting or causing to be presented a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil

penalties for each false claim. For penalties assessed after December 13, 2021, whose associated violations occurred after November 2, 2015, the penalties range from \$11,803 to \$23,607 for each false claim. The minimum and maximum per claim penalty amounts are subject to annual increases for inflation.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and some of these state laws apply where a claim is submitted to any third-party payer and not only a governmental payer program.

Additionally, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have knowingly presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or for a claim that is false or fraudulent. This law also prohibits the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for items or services reimbursable by Medicare or a state healthcare program. There are several exceptions to the prohibition on beneficiary inducement.

The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs, to include private insurance (i.e., it is an "all payer" statute). For purposes of EKRA, the term "laboratory" is defined broadly and without reference to any connection to substance use disorder treatment. EKRA is a criminal statute and violations can result in fines of up to \$200,000, up to 10 years in prison, or both, per violation. The law includes a limited number of exceptions, some of which closely align with corresponding federal Anti-Kickback Statute exceptions and safe harbors and others that materially differ.

We are also subject to the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. In Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act 2010, faces imprisonment of up to ten years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, also imposed annual reporting requirements on entities including manufacturers of certain devices, medical supplies, drugs and biologics for certain payments and transfers of value that the manufacturer provides, directly or indirectly, to or on behalf of physicians (defined to include various healthcare professionals such as doctors, physician assistants, and nurse practitioners) and teaching hospitals. The Physician Payments Sunshine Act also requires entities including applicable manufacturers to report certain ownership and investment interests held by physicians and their immediate family members in such manufacturers. In addition, certain states, such as Vermont and Massachusetts, have enacted laws that impose certain reporting requirements for payments and transfers of value provided to covered healthcare providers. These state laws are not preempted by the federal Physician Payments Sunshine Act to the extent the state law requires the reporting of information that is not required to be reported under the federal Physician Payments Sunshine Act. Finally, certain states such as Massachusetts, Nevada, and Vermont have enacted laws that limit or prohibit the provision of payments or other transfers of value to covered recipients, such as certain health care providers, hospitals, and health benefit plan administrators.

Physician referral prohibitions

A federal law directed at "self-referrals," commonly known as the "Stark Law," prohibits a physician from referring a patient to an entity for certain Medicare-covered designated health services, including laboratory services, if the physician, or an immediate family member, has a financial relationship with the entity, unless an exception applies. The Stark Law also prohibits an entity from billing for services furnished pursuant to a prohibited referral. A physician or entity that engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to \$174,172 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to civil monetary penalties of up to \$26,125 per service, an assessment of up to three times the amount claimed and possible exclusion from participation in federal healthcare programs. Bills submitted in violation of the Stark Law may not be paid by

Medicare, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states have comparable laws that apply to services covered by other third-party payers. The Stark Law also prohibits state receipt of federal Medicaid matching funds for services furnished pursuant to a prohibited referral. This provision of the Stark Law has not been implemented by regulations, but some courts have held that the submission of claims to Medicaid that would be prohibited as self-referrals under the Stark Law for Medicare could implicate the False Claims Act.

Corporate practice of medicine

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging clinicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. For example, California's Medical Board has indicated that determining what diagnostic tests are appropriate for a particular condition and taking responsibility for the ultimate overall care of the patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings.

Intellectual property

We rely on a combination of intellectual property rights, including trade secrets, copyrights, trademarks, customary contractual protections and, to a lesser extent, patents, to protect our core technology and intellectual property. With respect to patents, we believe that the practice of patenting individual genes, along with patenting tools and methods specific to individual genes, has impeded the progress of the genetic testing industry beyond single gene tests and is antithetical to our core principle that patients should own and control their own genomic information. The U.S. Supreme Court has issued a series of unanimous (9-0) decisions setting forth limits on the patentability of natural phenomena, natural laws, abstract ideas and their applications — *i.e.*, *Mayo Collaborative v. Prometheus Laboratories (2012)*, or *Mayo, Association for Molecular Pathology v. Myriad Genetics (2013)*, or *Myriad*, and *Alice Corporation v. CLS Bank (2014)*, or *Alice*. As discussed below, we believe the *Mayo*, *Myriad* and *Alice* decisions bring clarity to the limits to which patents may cover specific genes, mutations of such genes, or gene-specific technology for determining a patient's genomic information.

Patents

U.S. Supreme Court cases have clarified that naturally occurring DNA sequences are natural phenomena, which should not be patentable. On June 13, 2013, the U.S. Supreme Court decided *Myriad*, a case challenging the validity of patent claims held by Myriad relating to the cancer genes BRCA1 and BRCA2. The *Myriad* Court held that genomic DNAs that have been isolated from, or have the same sequence as, naturally occurring samples, such as the DNA constituting the BRCA1 and BRCA2 genes or fragments thereof, are not eligible for patent protection. Instead, the *Myriad* Court held that only those complementary DNAs (cDNAs) which have a sequence that differs from a naturally occurring fragment of genomic DNA may be patent eligible. Because it will be applied by other courts to all gene patents, the holding in *Myriad* also invalidates patent claims to other genes and gene variants. Prior to *Myriad*, on August 16, 2012, the U.S. Court of Appeals for the Federal Circuit had held that certain patent claims of Myriad directed to methods of comparing or analyzing BRCA1 and BRCA2 sequences to determine whether or not a person has a variant or mutation are unpatentable abstract processes, and Myriad did not appeal such ruling.

We do not currently have any patents or patent applications directed to the sequences of specific genes or variants of such genes, nor do we rely on any such in-licensed patent rights of any third party. We believe that correlations between specific gene variants and a person's susceptibility to certain conditions or diseases are natural laws that are not patentable under the U.S. Supreme Court's decision in *Mayo*. The *Mayo* case involved patent claims directed to optimizing, on a patient-specific basis, the dosage of a certain drug by measuring its metabolites in a patient. The *Mayo* Court determined that patent claims directed at detection of natural correlations, such as the correlation between drug metabolite levels in a patient and that drug's optimal dosage for such patient, are not eligible for patent protection. The *Mayo* Court held that claims based on this type of comparison between an observed fact and an understanding of that fact's implications represent attempts to patent a natural law and, moreover, when the processes for making the comparison are not themselves sufficiently inventive, claims to such processes are similarly patent-ineligible. On June 19, 2014, the U.S. Supreme Court decided *Alice*, where it amplified its *Mayo* and *Myriad* decisions and clarified the analytical framework for distinguishing between patents that claim laws of nature, natural phenomena and abstract ideas and those that claim patent-eligible applications of

such concepts. According to the *Alice* Court, the analysis depends on whether a patent claim directed to a law of nature, a natural phenomenon or an abstract idea contains additional elements, an “inventive concept,” that “is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself;” (citing *Mayo*).

We believe that *Mayo*, *Myriad* and *Alice* not only render as unpatentable genes, gene fragments and the detection of a person’s sequence for a gene, but also have the same effect on generic applications of conventional technology to specific gene sequences. For example, we believe that generic claims to primers or probes directed to specific gene sequences and uses of such primers and probes in determining a person’s genetic information are not patentable. We do not currently have any patents or patent applications directed to such subject matter nor have we in-licensed such patents rights of any third party.

Unlike patents directed to specific genes, we do rely upon, in part, patent protection to protect technology that is not gene-specific and that provides us with a potential competitive advantage as we focus on making comprehensive genetic information less expensive and more broadly available to our customers. In this regard, we have issued U.S. patents, pending U.S. patent applications and corresponding non-U.S. patents and patent applications directed to various aspects of our laboratory, analytic and business practices. We intend to pursue further patent protection where appropriate.

For information regarding legal actions that pertain to intellectual property rights, see Note 8, “Commitments and contingencies” in Notes to Consolidated Financial Statements in Part II, Item 8 of this report.

Trade secrets

In addition to seeking patent protection for some of our laboratory, analytic and business practices, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain and develop our competitive position. We have developed proprietary procedures for both the laboratory processing of patient samples and the analysis of the resulting data to generate clinical reports. For example, we have automated aspects of our processes for curating information about known variants, identifying variants in an individual’s sequence information, associating those variants with known information about their potential effects on disease, and presenting that information for review by personnel responsible for its interpretation and for the delivery of test reports to clinicians and patients. We try to protect these trade secrets, in part, by taking reasonable steps to keep them confidential. This includes entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees and certain third parties. We also enter into invention or patent assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we may not enter into such agreements with all relevant parties, and these parties may not abide by the terms of their agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy or independently develop and commercially exploit aspects of our technology or obtain and use information that we regard as proprietary.

Trademarks

We work hard to achieve a high level of quality in our operations and to provide our customers with a superior experience when interacting with us. As a consequence, our brand is very important to us, as it is a symbol of our reputation and representative of the goodwill we seek to generate with our customers. As a consequence, we have invested significant resources in protection of our trademarks.

Environmental matters

We are committed to maintaining compliance with all environmental laws applicable to our operations and products, and also realize that we need to begin to take steps to address our environmental footprint. We take our responsibility for environmental stewardship seriously and believe that we must do our part in addressing global climate change challenges. While we are early on this journey, we are committed to reducing our environmental impact. We aim to integrate sustainable business practices, energy-efficient technologies and eco-friendly products that advance our progress in reducing our carbon footprint, water consumption and waste.

We realize that our effectiveness in executing upon our environmental objectives first begins with understanding our environmental impact and carbon footprint. We engaged a third-party to complete an in-depth analysis of our 2020 and 2021 emissions, water and waste data. With this insight, we established a baseline from which to facilitate ongoing internal measuring, managing and reporting of these factors. We believe this foundation now better positions us to improve internal tracking systems, launch eco-friendly initiatives, normalize our metrics and establish science-based targets to reduce our environmental footprint over time.

Our operations require the use of hazardous materials (including biological materials) that subject us to a variety of federal, state and local environmental and safety laws and regulations. Some of these regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or new regulations will affect our business, operations or the cost of compliance.

Raw materials and suppliers

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Agena Bioscience, Inc., Illumina, Inc., Integrated DNA Technologies Incorporated, Roche Holdings Ltd., QIAGEN, Inc. and Twist Bioscience Corporation for certain laboratory reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We are in active litigation with affiliates of QIAGEN, Inc. as described in Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this report. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers and QIAGEN, Inc. to provide the enzymes that we use in our products. Our operations could be interrupted if we encounter delays or difficulties in securing these reagents and enzymes, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our operations, including sequencers and various associated reagents and enzymes. The use of equipment or materials provided by these replacement suppliers would require us to alter our operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot be certain that we will be able to secure alternative equipment, reagents and other materials, or bring such equipment, reagents and materials on line and revalidate them without experiencing interruptions in our workflow. If we encounter delays or difficulties in securing, reconfiguring or revalidating equipment and materials, our business and reputation could be adversely affected.

Customer concentration and seasonality

We receive payment for our products and services from patients, biopharmaceutical partners, third-party payers and other business-to-business customers. As of December 31, 2021, our revenue has been primarily derived from test reports generated from our assays. See information regarding our customer concentration in Note 2, "Summary of significant accounting policies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

We have historically experienced higher revenue in our fourth quarter compared to other quarters in our fiscal year due in part to seasonal demand of our tests from patients who have met their annual insurance deductible. However, changes in our product and payer mix might cause these historical seasonal patterns to be different than future patterns of revenue or financial performance.

Human capital resources

Our people

The strength of our team and the culture in which we work is essential to our ability to achieve our broader mission. Attracting, developing and retaining exceptional employees is vitally important to us, but we also invest in creating a differentiated culture for our team that is designed to enable continuous innovation at scale. We want Invitae to be a force for good, a team that is helping make genetics and healthcare equally accessible to all.

We had approximately 3,000 employees as of December 31, 2021, of which approximately 55% are women and 45% men. Our management team is 25% women and 75% men, and our Board is 50% women and 50% men.

Our culture and mission

Our team is driven to make a difference for the patients we serve. We aim to be a highly functioning and collaborative team, well equipped to attract, acquire, onboard, develop and retain diverse talent and teams while leading culture and change management in support of business objectives. Our People & Culture business partners are embedded within leadership teams to help support our talent strategy throughout our organization.

Our total rewards philosophy

We aim to create a culture where our employees thrive and innovate at scale. We encourage an environment where employees are empowered to speak up, try new things and make decisions that push us forward. We provide employees with opportunities to grow and advance, supported by flexible work hours, flexible paid time off (uncapped, non-accrual), the ability to work remotely for many roles and the satisfaction of doing meaningful work.

We offer a competitive total rewards package, which includes base compensation, incentive compensation, equity, healthcare and insurance coverage, 401(k) (with a partial match), and a broad range of other benefits.

Our generous parental leave benefits are offered to new parents. This past year, we introduced a new health vendor to provide fertility and adoption benefits for our U.S. population as well as most of our global employees. Additionally, we have an employer-sponsored testing program, which provides employees and their covered dependents access to all of our genetic testing at no cost.

Diversity, Equity and Inclusion, or DEI

Our DEI mission is to engage, develop and retain talent from diverse backgrounds by fostering community, providing education and support, and advancing inclusive research and health equity globally. Our vision is to cultivate a place where we all belong. Today, 20% of employees are members of one or more of our nine active employee resource groups. And in attracting new employees, our hiring process has been designed to provide an equitable candidate experience, facilitate the inclusion of new perspectives, foster innovation and creativity, and leverage technology and data analytics to address gaps in representation. As of December 31, 2021, approximately 63% of our workforce was White, 18% Asian, 8% Hispanic, 5% Black or African American, 4% two or more races (not Hispanic or Latino) and 2% not self-identified based on our payroll system and individual self-identification. On our management team, 37% are people who identify as non-White and on our Board 33% so identify.

People development

We empower our employees to own their career path and seek out training programs to take them to the next level. We have invested in our training and development programs and infrastructure for our employees. Our Leadership Principles were introduced in January 2021. The ten principles capture what we have found to be critical skills and observable behaviors that best help our team deliver results. The Leadership Principles link all talent processes including hiring, talent development, differentiating performance, assessing potential, building a leadership pipeline, maintaining a strong leadership bench and succession planning.

People engagement

As part of our commitment to data-driven decision making, we conduct a monthly "Morale Survey" that asks our teammates three questions: how they feel about the company's direction, what's going well, and what's not going well. We've been asking these questions consistently for several years so we can quickly identify trends as they emerge and inform management decision-making. We also initiated quarterly team surveys to gauge how employees feel about the effectiveness of their teams and the identification of "helpers" and "blockers" to cross functional success. Our leadership teams get feedback from these surveys regarding manager effectiveness, as well as annual updates about the health of our culture to support continuous improvement. Our surveys have the option for employees to escalate their comments to People & Culture to address and follow-up.

Health and safety

We are committed to maintaining and improving the health and safety of our employees. All employees are responsible for maintaining a safe workplace. We promote, train and ensure employees are following our protocols, rules, policies and practices and are reporting accidents, injuries and unsafe equipment, practices or conditions, in accordance with our Code of Business Conduct and Ethics and health and safety policies. In addition, we established an Enterprise Crisis Management Team that, along with the Employee Health and Safety Administrator, comprise the Steering Committee for pandemic response responsible for ensuring our COVID-19 policies and practices meet all necessary standards and regulations. Our response has evolved as the situation has evolved.

Information about our executive officers

The names of our executive officers and other corporate officers, and their ages as of March 1, 2022, are as follows:

Name	Age	Position
Sean E. George, Ph.D.	48	President, Chief Executive Officer, Director and Co-Founder
Thomas R. Brida	51	General Counsel and Secretary
Kenneth D. Knight	61	Chief Operating Officer
Robert L. Nussbaum, M.D.	72	Chief Medical Officer
Yafei (Roxi) Wen	49	Chief Financial Officer
Robert F. Werner	48	Chief Accounting Officer

Sean E. George, Ph.D. is one of our co-founders and has been our President and Chief Executive Officer since January 2017, a position he also held from January 2010 through August 2012. Dr. George also served as our President since August 2012 and he served as our Chief Operating Officer from August 2012 until January 2017. He has also served as a director since January 2010. Prior to co-founding Invitae, Dr. George served as Chief Operating Officer from 2007 to November 2009 at Navigenics, Inc., a personalized medicine company. Previously, he served as Senior Vice President of Marketing and Senior Vice President, Life Science Business at Affymetrix, Inc., a provider of life science and molecular diagnostic products, as well as Vice President, Labeling and Detection Business at Invitrogen Corporation, a provider of tools to the life sciences industry, during his tenure there from 2002 to 2007. Dr. George currently serves as a director of CM Life Sciences, Inc., a publicly traded special purpose acquisition company. Dr. George holds a B.S. in Microbiology and Molecular Genetics from the University of California Los Angeles, an M.S. in Molecular and Cellular Biology from the University of California Santa Barbara, and a Ph.D. in Molecular Genetics from the University of California Santa Cruz.

Thomas R. Brida has served as our General Counsel since January 2017. Mr. Brida also served as our Deputy General Counsel from January 2016 to January 2017. Prior to joining Invitae, he was Associate General Counsel at Bio-Rad Laboratories, a life science research and clinical diagnostics manufacturer, from January 2004 to January 2016. He holds a B.A. from Stanford University and a J.D. from the U.C. Berkeley School of Law.

Kenneth D. Knight has served as our Chief Operating Officer since June 2020. Prior to that, he most recently served as Vice President of transportation services at Amazon.com, Inc., a multinational and diversified technology company, from December 2019 to June 2020, and as Vice President of Amazon's global delivery services, fulfillment operations and human resources from April 2016 to December 2019. Prior to his time at Amazon, from 2012 to March 2016, Mr. Knight served as general manager of material handling and underground business division at Caterpillar Inc., a manufacturer of machinery and equipment. Prior to that, Mr. Knight served in various capacities at General Motors Company, a vehicle manufacturer, for 27 years, including as executive director of global manufacturing engineering and as manufacturing general manager. Mr. Knight holds a B.S. in Electrical Engineering from the Georgia Institute of Technology and a Master of Business Administration from the Massachusetts Institute of Technology.

Robert L. Nussbaum, M.D. has served as our Chief Medical Officer since August 2015. From April 2006 to August 2015, he was chief of the Division of Genomic Medicine at UCSF Health where he also held leadership roles in the Cancer Genetics and Prevention Program beginning in January 2009 and the Program in Cardiovascular Genetics beginning in July 2007. From April 2006 to August 2015, he served as a member of the UCSF Institute for Human Genetics. Prior to joining UCSF Health, Dr. Nussbaum was chief of the Genetic Disease Research Branch of the National Human Genome Research Institute, one of the National Institutes of Health, from 1994 to 2006. He is a member of the National Academy of Medicine and a fellow at the American Academy of Arts and Sciences. Dr. Nussbaum is a board-certified internist and medical geneticist who holds a B.S. in Applied Mathematics from Harvard College and an M.D. from Harvard Medical School in the Harvard-MIT joint program in Health Sciences and Technology. He completed his residency in internal medicine at Barnes-Jewish Hospital and a fellowship in medical genetics at the Baylor College of Medicine.

Yafei (Roxi) Wen has served as our Chief Financial officer since June 2021. Prior to Invitae, she served as the Chief Financial Officer at Mozilla Corporation, overseeing finance and accounting, mergers and acquisitions, business development, data and analytics, information technology and engineering operations, workplace resources and sustainability. Prior to Mozilla, Roxi served as the Chief Financial Officer at Elo Touch Solutions and General Electric Critical Power following experience driving capital market and business finance efforts at Medtronic, a leading medical technology company. Roxi is a CFA charterholder and has a Master of Business Administration from the University of Minnesota.

Robert F. Werner has served as our Chief Accounting and Principal Accounting Officer since May 2020. Prior to that, Mr. Werner served as our Corporate Controller from September 2017. Prior to joining Invitae, from February 2015 to September 2017, Mr. Werner served as Vice President of Finance and Corporate Controller of Proteus Digital Health, Inc., a digital medicine pharmaceuticals company. Prior to that, Mr. Werner served as Corporate Controller and Principal Accounting Officer of CardioDx, Inc., a molecular diagnostics company, from March 2012 to February 2015. Mr. Werner is a Certified Public Accountant in California and started his career at Ernst & Young LLP. Mr. Werner holds a Bachelor of Science in Accounting and a Master of Accountancy in Professional Accounting from Brigham Young University's Marriott School of Management.

General Information

We were incorporated in the State of Delaware on January 13, 2010 under the name Locus Development, Inc. and changed our name to Invitae Corporation in 2012.

Our principal executive offices are located at 1400 16th Street, San Francisco, California 94103, and our telephone number is (415) 374-7782. Our website address is www.invitae.com. The information contained on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

We make available free of charge on our website our Annual Reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC. You may obtain a free copy of these reports in the Investor Relations section of our website, www.invitae.com. All reports that we file are also available at www.sec.gov.

ITEM 1A. Risk Factors

Risks related to our business and strategy

We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.

We have incurred substantial losses since our inception. For the years ended December 31, 2021, 2020 and 2019, our net losses were \$379.0 million, \$602.2 million and \$242.0 million, respectively. At December 31, 2021, our accumulated deficit was \$1.7 billion. We expect to continue to incur significant losses as we invest in our business. We incurred research and development expenses of \$416.1 million, \$240.6 million and \$141.5 million and selling and marketing expenses of \$225.9 million, \$168.3 million and \$122.2 million in 2021, 2020 and 2019, respectively. We expect these losses may increase driven by increased investments in research and development and selling and marketing as we focus on scaling our business and operations and expanding our testing capabilities. We have also experienced and may continue to experience decreases in test volume due to the impact of COVID-19. Additionally, in 2021, widespread inflationary pressures were experienced across global economies, resulting in higher costs for our raw materials, non-material costs, labor and other business costs, and significant increases in the future could adversely affect our results of operations. In addition, as a result of the integration of acquired businesses, we may be subject to unforeseen or additional expenditures, costs or liabilities, including costs and potential liabilities associated with litigation. Our prior losses and expected future losses have had and may continue to have an adverse effect on our stockholders' equity, working capital and stock price. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We began operations in January 2010 and commercially launched our initial assay in late November 2013. Our prospects must be considered in light of the risks and difficulties frequently encountered by companies in a similar stage of development, particularly companies in new and rapidly evolving markets such as ours. These risks include an evolving and unpredictable business model and the management of growth. To address these risks, we must, among other things, increase our customer base; continue to implement and successfully execute our business and marketing strategy; identify, acquire and successfully integrate companies, assets or technologies in areas that are complementary to our business strategy; successfully enter into other strategic collaborations or relationships; obtain access to capital on acceptable terms and effectively utilize that capital; identify, attract, hire, retain, motivate and successfully integrate additional employees; continue to expand, automate and upgrade our laboratory, technology and data systems; obtain, maintain and expand coverage and reimbursement by healthcare payers; obtain and maintain sufficient payment by partners, institutions and individuals; provide rapid test turnaround times with accurate results at low prices; provide superior customer service; and respond to competitive developments. We cannot assure you that we will be successful in addressing these risks, and the failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure, commercial operations, research and development and selling and marketing activities and pursue acquisitions and integrate acquired businesses. We expect we will need to raise additional capital to finance operations prior to achieving profitability, or should we make additional acquisitions. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. In addition, the terms of our credit agreement restrict our ability to incur certain indebtedness and issue certain equity securities. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings, if available, could impose significant restrictions on our operations.

The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire companies or acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize

ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, selling and marketing initiatives, or potential acquisitions. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to our company.

We have acquired and may continue to acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.

As part of our business strategy, we have pursued and expect to continue to pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. Since 2017, we have acquired numerous companies, including companies in family health genetic information services, the patient data collection and platform industry, the non-invasive prenatal screen offering industry, the genetic information industry and the use of artificial intelligence in such industry, the pharmacogenetic testing industry, the oncology industry and the infectious disease industry.

With respect to our acquired businesses and any acquisitions we may make in the future, we may not be able to integrate these businesses successfully into our existing business, and we could assume unknown or contingent liabilities. For example, if we are unable to integrate ArcherDX's technology, people and distributed products business model into our existing business, we will not realize the expected benefits of that acquisition. Any acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Furthermore, as we experienced in the past, the loss of customers, payers, partners, suppliers or key management following the completion of any acquisitions by us could harm our business. Changes in services, sources of revenue, and branding or rebranding initiatives may involve substantial costs and may not be favorably received by customers, resulting in an adverse impact on our financial results, financial condition and stock price. Integration of an acquired company or business also may require management's time and resources that otherwise would be available for ongoing development of our existing business. We may also need to divert cash from other uses to fund these integration activities and these new businesses. Ultimately, we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment, or these benefits may take longer to realize than we expected.

In connection with certain of our completed acquisitions, we have agreed to pay cash and/or stock consideration that is contingent upon the achievement of specified objectives, such as development objectives, regulatory submissions, regulatory approvals and revenue related to certain products. As of the date of the applicable acquisition, we record a contingent liability representing the estimated fair value of the contingent consideration we expect to pay. On a quarterly basis, we reassess these obligations and, in the event our estimate of the fair value of the contingent consideration changes, we record increases or decreases in the fair value as an adjustment to operating expense, which could have a material impact on our results of operations. As of December 31, 2021, we accrued \$1.9 million of contingent consideration, which is related to our acquisition of Genelex.

To finance any acquisitions or investments, we may raise additional funds, which could adversely affect our existing stockholders and our business. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. In addition, our stockholders may experience substantial dilution as a result of additional securities we may issue for acquisitions. Open market sales of substantial amounts of our common stock issued to stockholders of companies we acquire could also depress our stock price. Additional funds may not be available on terms that are favorable to us, or at all.

We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.

Our performance, including our research and development programs and laboratory operations, largely depend on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization, including software developers, geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel to process and interpret our genetic tests. In addition, we may need to continue to expand our sales force with qualified and experienced personnel. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. In addition, our compensation arrangements, such as

our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. If the value of our common stock declines significantly, as it has in the recent past, and remains depressed, or if we do not have enough shares authorized to grant equity awards to new and existing employees, it may prevent us from recruiting and retaining qualified employees. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to scale our business and support our research and development efforts and our clinical laboratory. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

We need to scale our infrastructure in advance of demand for our tests and other products and services, and our failure to generate sufficient demand for our products and services would have a negative impact on our business and our ability to attain profitability.

Our success depends in large part on our ability to extend our market position, to develop new products and services, to provide customers with high-quality test reports quickly and at a lower price than our competitors, and to achieve sufficient test volume to realize economies of scale. In order to execute our business model, we intend to continue to invest heavily in order to significantly scale our infrastructure, including our testing capacity and information systems, expand our commercial operations, customer service, billing and systems processes and enhance our internal quality assurance program. We expect that much of this growth will be in advance of demand for our tests and other products and services. Our current and future expense levels are to a large extent fixed and are largely based on our investment plans and our estimates of future revenue. Because the timing and amount of revenue from our products and services is difficult to forecast, when revenue does not meet our expectations, we may not be able to adjust our spending promptly or reduce our spending to levels commensurate with our revenue. Even if we are able to successfully scale our infrastructure and operations, we cannot assure you that demand for our products and services will increase at levels consistent with the growth of our infrastructure. If we fail to generate demand commensurate with this growth or if we fail to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition and results of operations could be adversely affected.

We face risks related to health epidemics, including the ongoing COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

Our business has been and could continue to be adversely affected by a widespread outbreak of contagious disease, including the pandemic of respiratory illness caused by a novel coronavirus known as COVID-19. Global health concerns relating to COVID-19 have negatively affected the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty.

The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. For example, some of our personnel located at our headquarters and other offices in California, elsewhere in the United States and in other countries, have been subject to shelter-in-place or stay-at-home orders from state and local governments. These measures have adversely impacted and may further impact our employees and operations and the operations of our customers, suppliers and business partners, and may continue to negatively impact spending patterns, payment cycles and insurance coverage levels. These measures have adversely affected and may continue to adversely affect demand for our tests. In 2020, many of our customers, including hospitals and clinics, suspended non-emergency appointments and services, which resulted in a significant decrease in our test volume. Travel bans, restrictions and border closures have also impacted our ability to ship tests to and receive samples from our customers. While some of these measures have been lifted, they may be implemented again if COVID-19 is not contained or a new surge occurs. These measures have adversely affected and may continue to adversely affect our test volume, sales activities and results of operations.

The spread of COVID-19 caused us to modify our business practices (including employee travel, mandating that all non-essential personnel work from home, temporary closures of our offices, cancellation of physical participation in sales activities, meetings, events and conferences and increasing inventories of certain supplies because we have experienced supply delays and disruptions as a result of the COVID-19 pandemic and have also had to obtain supplies from new suppliers). We may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers and business partners. Such actions have impacted our ability to fully integrate businesses we have acquired and may impact those we may acquire in the future. There is no certainty that such actions will be sufficient to mitigate the risks posed by the virus or otherwise be satisfactory to government authorities. If significant portions of our workforce are unable to work

effectively, including due to illness, quarantines, social distancing, government actions or other restrictions in connection with COVID-19, our operations will be impacted.

The extent to which COVID-19 continues to impact our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration and spread of the pandemic, the actions to contain the virus and treat its impact, and how quickly and to what extent normal economic and operating activities can resume. COVID-19 could limit the ability of our customers, suppliers and business partners to perform, including third-party payers' ability to make timely payments to us during and following the pandemic. Some of our biopharmaceutical partners have been impacted by COVID-19, which has delayed certain programs and impacted the timing of our revenue. We have also experienced and may continue to experience a shortage of, or delays in, laboratory supplies and equipment, or a suspension of services from other laboratories or third parties. Even after COVID-19 has subsided, we may continue to experience an adverse impact to our business as a result of its global economic impact, including any recession that has occurred or may occur in the future, and loss of health insurance coverage resulting from pandemic-related job losses.

Specifically, difficult macroeconomic conditions, such as cost inflation, decreases in per capita income and level of disposable income, increased and prolonged unemployment or a decline in consumer confidence as a result of COVID-19, as well as limited or significantly reduced points of access of our tests, could have a material adverse effect on the demand for our tests. Under difficult economic conditions, consumers may seek to reduce discretionary spending by forgoing our tests. Decreased demand for our tests, particularly in the United States, has negatively affected and could continue to negatively affect our overall financial performance.

There are no comparable recent events which may provide guidance as to the effect of the spread of COVID-19, and, as a result, the ultimate impact of COVID-19 or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of COVID-19's impact on our business, our operations, or the global economy as a whole. However, the effects could have a material impact on our results of operations, and we continue to monitor the situation closely.

To the extent the COVID-19 pandemic continues to adversely affect our business and financial results, it may also have the effect of heightening many of the other risks described in this section.

If third-party payers, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.

Our ability to increase the number of billable tests and our revenue will depend on our success achieving reimbursement for our tests from third-party payers. Reimbursement by a payer may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary, cost-effective and has received prior authorization. The commercial success of our distributed products, including our therapy selection in vitro diagnostic, or IVD, products and our Personalized Cancer Monitoring product, or PCM, if approved, will depend on the extent to which our customers receive coverage and adequate reimbursement from third-party payers, including managed care organizations and government payers (e.g., Medicare and Medicaid).

Since each payer makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payer to cover and the amount it will reimburse for our tests will likely be made on an indication-by-indication basis. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our germline tests from most of the large commercial third-party payers in the United States, and the Centers for Medicare & Medicaid Services, or CMS, provides reimbursement for our multi-gene tests for hereditary breast and ovarian cancer-related disorders as well as colon cancer. We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from third-party payers may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive and may not result in payment. In cases where there is not a contracted rate for reimbursement, there is typically a greater coinsurance or co-payment requirement from the patient, which may result in further delay or decreased likelihood of collection.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payer to payer, and we have needed additional time and resources to comply with them. We have also experienced, and may continue to experience, delays in or denials of coverage if we do not adequately comply with these requirements. Our third-party payers have also requested, and in the future may request, audits of the amounts paid to us. We have been required to repay certain amounts to payers as a result of such audits, and we could be

adversely affected if we are required to repay other payers for alleged overpayments due to lack of compliance with their reimbursement policies. In addition, we have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests and any future tests we may develop or acquire. If we fail to expand and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the markets in which we operate. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.

With the development of next generation sequencing, the clinical genetics market is becoming increasingly competitive, and we expect this competition to intensify in the future. We face competition from a variety of sources, including:

- dozens of relatively specialized competitors focused on genetics applied to healthcare, such as Ambry Genetics, a subsidiary of Konica Minolta Inc.; Athena Diagnostics and Blueprint Genetics, subsidiaries of Quest Diagnostics Incorporated; Baylor-Miraca Genetics Laboratories; Caris Life Sciences, Inc.; Centogene AG; Color Genomics, Inc.; Connective Tissue Gene Test LLC, a subsidiary of Health Network Laboratories, L.P.; Cooper Surgical, Inc.; Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Foundation Medicine, a subsidiary of Roche Holding AG; Fulgent Genetics, Inc.; Guardant Health, Inc.; Integrated Genetics, Sequenom Inc., Correlagen Diagnostics, Inc., and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings; Myriad Genetics, Inc.; Natera, Inc.; Perkin Elmer, Inc.; and Sema4 Genomics; as well as other commercial and academic labs;
- a few large, established general testing companies with large market share and significant channel power, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated;
- a large number of clinical laboratories in an academic or healthcare provider setting that perform clinical genetic testing on behalf of their affiliated institutions and often sell and market more broadly; and
- a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness including Illumina, Inc., which is also one of our suppliers.

Hospitals, academic medical centers and eventually physician practice groups and individual clinicians may also seek to perform at their own facilities the type of genetic testing we would otherwise perform for them. In this regard, continued development of equipment, reagents, and other materials as well as databases and interpretation services may enable broader direct participation in genetic testing and analysis.

Participants in closely related markets such as clinical trial or companion diagnostic testing could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide such potential competitors with significant advantages.

In addition, the biotechnology and genetic testing fields are intensely competitive both in terms of service and price, and continue to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

We also face competition as a result of our 2020 acquisition of ArcherDX and our 2021 acquisition of Ciitizen. In particular, ArcherDX competes with numerous companies in the life sciences research, clinical diagnostics and drug development spaces, including, among others, Natera, QIAGEN N.V., Guardant Health, Inc., Thermo Fisher, Inc., Foundation Medicine, Caris Life Sciences, Inc., Tempus, Laboratory Corporation of America, Quest Diagnostics, Inc., NeoGenomics, Inc., BioReference Laboratories, Inc. and Illumina, Inc. Ciitizen competes with companies in the patient data platform business, including, among others, Picnic Health, All Stripes, Seqster, Apple, Flatiron Health, and Tempus.

We believe the principal competitive factors in our market are:

- breadth and depth of content;
- quality;
- reliability;

- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;
- convenience of testing;
- brand recognition of test provider;
- additional value-added services and informatics tools;
- client service; and
- quality of website content.

Many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, higher margins on their tests, substantially greater financial, technological and research and development resources, selling and marketing capabilities, lobbying efforts, and more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do, sell their tests at prices designed to win significant levels of market share, or obtain reimbursement from more third-party payers and at higher prices than we do. We may not be able to compete effectively against these organizations. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payers are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies as use of next generation sequencing for clinical diagnosis and preventative care increases. Certain of our competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to website and systems development than we can. In the past, our competitors have been successful in recruiting our employees and may continue to recruit qualified employees from us. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. Some of our competitors have obtained approval or clearance for certain of their tests from the U.S. Food and Drug Administration, or FDA. If payers decide to reimburse only for tests that are FDA-approved or FDA-cleared, or if they are more likely to reimburse for such tests, we may not be able to compete effectively unless we obtain similar approval or clearance for our tests. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.

Our expected future growth could create a strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, technology services, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as it grows. We may need to continue expanding our sales force to facilitate our growth, and we may have difficulties locating, recruiting, training and retaining sales personnel. Our ability to manage our growth effectively will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. As we grow, any failure of our controls or interruption of our production facilities or systems could have a negative impact on our business and financial operations. We plan to implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain, and failure to complete these activities in a timely and efficient manner could adversely affect our operations. Future growth in our business could also make it difficult for us to maintain our corporate culture. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

The market for patient data software is competitive, and our business will be adversely affected if we are unable to successfully compete.

The market for patient data software is competitive. Other than product innovation and access to healthcare data, there are no substantial barriers to entry in this market, and established or new entities may enter this market in

the future. While software internally developed by enterprises represents indirect competition, we also compete directly with packaged application software vendors. In addition, we face actual or potential competition from larger companies such as Apple, and similar companies that may attempt to sell customer engagement software to their installed base.

We believe competition will continue to be substantial as current competitors increase the sophistication of their offerings and as new participants enter the market. Many of our current and potential competitors have longer operating histories, larger customer bases, broader brand recognition, and significantly greater financial, marketing and other resources. With more established and better-financed competitors, these companies may be able to undertake more extensive marketing campaigns, adopt more aggressive pricing policies, and make more attractive offers to businesses to induce them to use their products or services. If we are unable to compete successfully, our business will be adversely affected.

Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including protected health information, or PHI, personally identifiable information, genetic information, credit card information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive patient data through our various customer tools and platforms. In addition to storing and transmitting sensitive data that is subject to multiple legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. In addition, there has recently been a significant increase in ransomware attacks, which could result in substantial harm to internal systems necessary for running our critical operations and revenue generating services.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take what we believe to be reasonable and appropriate measures, including a formal, dedicated enterprise security program, to protect sensitive information from various compromises (including unauthorized access, disclosure, or modification or lack of availability), our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. For example, we have been subject to phishing incidents in the past, and we may experience additional incidents in the future. Any such breach or interruption could compromise our networks, and the information stored therein could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business.

In addition to data security risks, we also face privacy risks. Should we actually violate, or be perceived to have violated, any privacy promises we make to patients or consumers, we could be subject to a complaint from an affected individual or interested privacy regulator, such as the FTC, a state Attorney General, an EU Member State Data Protection Authority, or a data protection authority in another international jurisdiction. This risk is heightened given the sensitivity of the data we collect.

Any security compromise that causes an apparent privacy violation could also result in legal claims or proceedings; liability under federal, state, foreign, or multinational laws that regulate the privacy, security, or breach of personal information, such as but not limited to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, state data security and data breach notification laws, the European Union's General Data Protection Regulation, or

GDPR, and the UK Data Protection Act of 2018; and related regulatory penalties. Penalties for failure to comply with a requirement of HIPAA or HITECH vary significantly, and, depending on the knowledge and culpability of the HIPAA-regulated entity, may include civil monetary penalties of up to \$1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to \$50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Penalties for unfair or deceptive acts or practices under the FTC Act or state Unfair and Deceptive Acts and Practices, or UDAP, statutes may also vary significantly.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. The GDPR took effect on May 25, 2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. The GDPR imposes strict requirements on controllers and processors of personal data, including enhanced protections for “special categories” of personal data, which includes sensitive information such as health and genetic information of data subjects. The GDPR also grants individuals various rights in relation to their personal data, including the rights of access, rectification, objection to certain processing and deletion. The GDPR provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, may result in significant administrative fines issued by EU regulators. Maximum penalties for violations of the GDPR are capped at 20M euros or 4% of an organization’s annual global revenue, whichever is greater.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 28, 2018, California adopted the California Consumer Privacy Act of 2018, or the CCPA. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of consumers who reside in California. Among other things, the CCPA confers to California consumers the right to receive notice of the categories of personal information that will be collected by a business, how the business will use and share the personal information, and the third parties who will receive the personal information; the CCPA also confers rights to access, delete, or transfer personal information; and the right to receive equal service and pricing from a business after exercising a consumer right granted by the CCPA. In addition, the CCPA allows California consumers the right to opt out of the “sale” of their personal information, which the CCPA defines broadly as any disclosure of personal information to a third party in exchange for monetary or other valuable consideration. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure. California amended the law in September 2018 to exempt all PHI collected by certain parties subject to HIPAA, and further amended the law in September 2020 to clarify that de-identified data as defined under HIPAA will also be exempt from the CCPA. The California Attorney General’s final regulations implementing the CCPA took effect on August 14, 2020. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches resulting from a business’s failure to implement and maintain reasonable data security procedures that is expected to increase data breach litigation.

In addition, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, that is scheduled to go into effect on January 1, 2023. The CPRA would, among other things, amend the CCPA to give California residents the ability to limit the use of their sensitive information, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law. Virginia and Colorado have recently enacted similar privacy acts, and other jurisdictions in the United States are beginning to propose laws similar to the CCPA. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business, results of operations, and financial condition.

It is possible the GDPR, CCPA and other emerging United States and international data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy laws and regulations may differ from country to country and state to state, and our obligations under these laws and regulations vary based on the nature of our activities in the particular jurisdiction, such as whether we collect samples from individuals in the local jurisdiction, perform testing in the local jurisdiction, or process personal information regarding employees or other individuals in the local jurisdiction. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance

procedures in a manner adverse to our business. We can provide no assurance that we are or will remain in compliance with diverse privacy and data security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and data security requirements could result in a variety of consequences, including civil or criminal penalties, litigation, or damage to our reputation, any of which could have a material adverse effect on our business.

If we are not able to continue to generate substantial demand of our tests, our commercial success will be negatively affected.

Our business model assumes that we will be able to generate significant test volume, and we may not succeed in continuing to drive adoption of our tests to achieve sufficient volumes. Inasmuch as detailed genetic data from broad-based testing panels such as our tests have only recently become available at relatively affordable prices, the continued pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes. Given the substantial amount of additional information available from a broad-based testing panel such as ours, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate further demand for our tests, we will need to continue to make clinicians aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. A lack of or delay in clinical acceptance of broad-based panels such as our tests would negatively impact sales and market acceptance of our tests and limit our revenue growth and potential profitability. Genetic testing can be expensive and many potential customers may be sensitive to pricing. In addition, potential customers may not adopt our tests if adequate reimbursement is not available, or if we are not able to maintain low prices relative to our competitors. Also, we may not be successful in increasing demand for our tests through our direct channel, in which we facilitate the ordering of our genetic tests by consumers through an online network of physicians.

If we are not able to generate demand for our tests at sufficient volume, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition and results of operations could be materially harmed.

We have devoted a portion of our resources to the development and commercialization of our therapy selection IVDs and to research and development activities related to our PCM product for cancer monitoring, including clinical and regulatory initiatives to obtain diagnostic clearance and marketing approval. The demand for these regulated products is unproven, and we may not be successful in achieving market awareness and demand for these products through our sales and marketing operations.

If our therapy selection IVDs and PCM products and related services do not perform as expected, we may not realize the expected benefits of our acquisition of ArcherDX.

The success of our therapy selection IVDs and PCM products depends on the market's confidence that we can provide reliable products that enable high quality diagnostic testing with high sensitivity and specificity and short turnaround times. There is no guarantee that the accuracy and reproducibility we demonstrated in the research use only, or RUO, market will continue as we launch commercial IVD products and our product deliveries increase and product portfolio expands.

Our RUO products, therapy selection IVDs and PCM products and related services use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. An operational, technological or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate or result in longer than expected turnaround times. In addition, laboratories are required to validate their processes before using these products for clinical purposes. These validations are outside of our control. If our products do not perform, or are perceived to not have performed, as expected or favorably to competitive products, our consolidated operating results, reputation, and business will suffer, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies.

In addition, we plan to match our test reports for therapy selection IVDs to identified mutations with FDA-approved targeted therapies or relevant clinical trials of targeted therapies. If a patient or physician who orders a test using one of our products is unable to obtain, or be reimbursed for the use of, targeted therapies because they are not indicated in the FDA-approved label for treatment, the patient is unable to enroll in an identified clinical trial due to the enrollment criteria of the trial, or some other reason, the ordering physician may conclude the test report does not contain actionable information. If physicians do not believe our products consistently generate actionable information

about their patients' disease or condition, they may be less likely to use our products. Any of the foregoing could have a material adverse effect on our ability to realize the intended benefits of our acquisition of ArcherDX.

Furthermore, we cannot provide assurance that customers will always use these products in the manner in which intended. Any intentional or unintentional misuse of these products by customers could lead to substantial civil and criminal monetary and non-monetary penalties, and could result in significant legal and investigatory fees.

The future growth of our distributed products business is partially dependent upon regulatory approval and market acceptance of our IVD products.

We anticipate that the future success of our distributed products business will depend in large part on our ability to effectively introduce enhanced or new offerings of IVD products. The development and launch of enhanced or new products and services, whether RUO or IVD, require the completion of certain clinical development and commercialization activities that are complex, costly, time-intensive and uncertain, and require us to accurately anticipate patients', providers' and, if applicable, payers' attitudes and needs and emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that we will not achieve its goals on a timely basis, or at all.

We have limited experience commercializing IVD products. We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new products or new services and result in increased costs and the diversion of management's attention and resources from other business matters.

An important factor in our ability to commercialize our distributed products is collecting data that supports their value proposition. The data collected from any studies we complete may not be favorable or consistent with its existing data or may not be statistically significant or compelling to the medical community or to third-party payers seeking such data for purposes of determining coverage for these products. This is particularly true with respect to service defects and errors. Any of the foregoing could have a negative impact on our ability to commercialize our future products, which could have a material adverse effect on the growth of our business and our results of operations.

Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.

Our success depends on our ability to provide reliable, high-quality tests that incorporate rapidly evolving information about the role of genes and gene variants in disease and clinically relevant outcomes associated with those variants. Errors, such as failure to detect genomic variants with high accuracy, or mistakes, such as failure to identify, or incompletely or incorrectly identifying, gene variants or their significance, could have a significant adverse impact on our business.

Hundreds of genes can be implicated in some disorders, and overlapping networks of genes and symptoms can be implicated in multiple conditions. As a result, a substantial amount of judgment is required in order to interpret testing results for an individual patient and to develop an appropriate patient report. We classify variants in accordance with published guidelines as benign, likely benign, variants of uncertain significance, likely pathogenic or pathogenic, and these guidelines are subject to change. In addition, it is our practice to offer support to clinicians and geneticists ordering our tests regarding which genes or panels to order as well as interpretation of genetic variants. We also rely on clinicians to interpret what we report and to incorporate specific information about an individual patient into the physician's treatment decision.

The marketing, sale and use of our genetic tests could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on, information we provide to clinicians, geneticists or patients, and lead to claims against us if someone were to allege that a test failed to perform as it was designed, if we failed to correctly interpret the test results, if we failed to update the test results due to a reclassification of the variants according to new published guidelines, or if the ordering physician were to misinterpret test results or improperly rely on them when making a clinical decision. In addition, our entry into the reproductive health and pharmacogenetic testing markets expose us to increased liability. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain liability insurance, including for errors and omissions, we cannot assure you that such insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our

reputation or cause us to suspend sales of our tests. The occurrence of any of these events could have an adverse effect on our reputation and results of operations.

Our industry is subject to rapidly changing technology and new and increasing amounts of scientific data related to genes and genetic variants and their role in disease. Our failure to develop tests to keep pace with these changes could make us obsolete.

In recent years, there have been numerous advances in methods used to analyze very large amounts of genomic information and the role of genetics and gene variants in disease and treatment therapies. Our industry has and will continue to be characterized by rapid technological change, increasingly larger amounts of data, frequent new testing service introductions and evolving industry standards, all of which could make our tests obsolete. Our future success will also depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. Our tests could become obsolete and our business adversely affected unless we continually update our offerings to reflect new scientific knowledge about genes and genetic variations and their role in diseases and treatment therapies.

Our success will depend in part on our ability to generate sales using our internal sales team and through alternative marketing strategies.

We may not be able to market or sell our current tests and any future tests we may develop or acquire effectively enough to drive demand sufficient to support our planned growth. We currently sell our tests primarily through our internal sales force. Historically, our sales efforts have been focused primarily on hereditary cancer and more recently on reproductive health. Our efforts to sell our tests to clinicians and patients outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. In addition, following the acquisition of ArcherDX, our sales efforts have expanded to include distributed products sold to laboratories. In the past, we have increased our sales force each year in order to drive our growth. In addition to the efforts of our sales force, future sales will depend in large part on our ability to develop and substantially expand awareness of our company and our tests through alternative strategies including through education of key opinion leaders, through social media-related and online outreach, education and marketing efforts, and through focused channel partner strategies designed to drive demand for our tests. We also plan to continue to spend on consumer advertising in connection with our direct channel to consumers, which could be costly. We have limited experience implementing these types of marketing efforts. We may not be able to drive sufficient levels of revenue using these sales and marketing methods and strategies necessary to support our planned growth, and our failure to do so could limit our revenue and potential profitability.

We also use a limited number of distributors to assist internationally with sales, logistics, education and customer support. Sales practices utilized by our distributors that are locally acceptable may not comply with sales practices standards required under U.S. laws that apply to us, which could create additional compliance risk. If our sales and marketing efforts are not successful outside the United States, we may not achieve significant market acceptance for our tests outside the United States, which could adversely impact our business.

Impairment in the value of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.

We record goodwill and intangible assets at fair value upon the acquisition of a business. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired. Goodwill and indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of our reporting unit could result in an impairment of goodwill or intangible assets and, in turn, a charge to net income. Any such charges could have a material adverse effect on our results of operations or financial condition.

We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments, materials and services, and we may not be able to find replacements or immediately transition to alternative suppliers.

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Illumina, Inc., Integrated DNA Technologies Incorporated, Qiagen N.V., Roche Holdings Ltd. and Twist Bioscience Corporation for certain laboratory substances used in the chemical reactions incorporated into our processes, which we refer to as reagents,

as well as sequencers and other equipment and materials which we use in our laboratory operations. We do not have short- or long-term agreements with most of our suppliers, and our suppliers could cease supplying these materials and equipment at any time, or fail to provide us with sufficient quantities of materials or materials that meet our specifications. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations could impact our supply chain and laboratory operations as well as our ability to conduct our tests, and it could take a substantial amount of time to integrate replacement equipment into our laboratory operations.

We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot assure you that we will be able to secure alternative equipment, reagents and other materials, and bring such equipment, reagents and materials online and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, we cannot assure you that replacement sequencers and associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business, financial condition, results of operations and reputation could be adversely affected.

Our planned therapy selection IVDs and PCM products are currently being developed to use only Illumina's sequencing platform. Without access to these sequencers, we would be unable commercialize these products. In addition, any efforts to validate these distributed products on additional sequencing platforms would require significant resources, expenditures and time and attention of our management, and there is no guarantee that we would be successful in implementing any such sequencing platforms in a commercially sustainable way.

We depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process and drug metabolism, our patient data platform, our clinical report optimization systems, our customer-facing web-based software, our customer reporting, and our various customer tools and platforms. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, customer relationship management, regulatory compliance and other infrastructure operations. In addition, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design, and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, and general administrative activities, including financial reporting.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to clinicians, billing payers, processing reimbursement appeals, handling physician or patient inquiries, conducting research and development activities, and managing the administrative and financial aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and results of operations.

Technical problems have arisen, and may arise in the future, in connection with our data and systems, including those that are hosted by third-party providers, which have in the past and may in the future result in interruptions in our business and operations. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

If our laboratories or other facilities become inoperable due to disasters, health epidemics or for any other reasons, we will be unable to perform our tests and our business will be harmed.

We perform all of our tests at our production facilities in San Francisco and Irvine, California, in Golden, Colorado, in Iselin, New Jersey, and in Seattle, Washington. We also plan to open a new laboratory and production facility in Morrisville, North Carolina. Our laboratories and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use. Our laboratories may be harmed or rendered inoperable or inaccessible due to natural or man-made disasters, including earthquakes, hurricanes, flooding, fire and power outages, or by health epidemics, such as the COVID-19 pandemic, which may render it difficult or impossible for us to perform our tests for some period of time. This risk of natural disaster is especially high for us since we perform the majority of our tests at our San Francisco laboratory, which is located in an active seismic region, and we do not have a redundant facility to perform the same tests in the event our San Francisco laboratory is inoperable. The inability to perform our tests or the backlog that could develop if our laboratories are inoperable for even a short period of time may result in the loss of customers or harm our reputation. If a natural disaster were to damage one of our facilities significantly or if other events were to cause our operations to fail or be significantly curtailed, we may be unable to manufacture our products, provide our services, or develop new products. For example, we temporarily closed our office in Boulder, Colorado and our warehouse in Louisville, Colorado following the December 2021 wildfire in Boulder County, Colorado. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all. The inability to open the planned facility in North Carolina, delays in opening such facility or failure to obtain required permits, licenses, or certifications could result in increased costs and prevent us from realizing the intended benefits of the new facility.

The loss of any member or change in structure of our senior management team could adversely affect our business.

Our success depends in large part upon the skills, experience and performance of members of our executive management team and others in key leadership positions. The efforts of these persons are critical to us as we continue to develop our technologies and test processes and focus on scaling our business. If we were to lose one or more key executives, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. All of our executives and employees are at-will, which means that either we or the executive or employee may terminate their employment at any time. We do not carry key person insurance for any of our executives or employees. In addition, we do not have a long-term retention agreement in place with our president and chief executive officer.

Development of new tests is a complex process, and we may be unable to commercialize new tests on a timely basis, or at all.

We cannot assure you that we will be able to develop and commercialize new tests on a timely basis. Before we can commercialize any new tests, we will need to expend significant funds in order to:

- conduct research and development;
- further develop and scale our laboratory processes; and
- further develop and scale our infrastructure to be able to analyze increasingly larger and more diverse amounts of data.

Our testing service development process involves risk, and development efforts may fail for many reasons, including:

- failure of any test to perform as expected;
- lack of validation or reference data; or
- failure to demonstrate utility of a test.

As we develop tests, we will have to make significant investments in development, marketing and selling resources. In addition, competitors may develop and commercialize competing tests faster than we are able to do so.

Our research and development efforts to add additional indications to our IVD products, if approved, will be hindered if we are not able to contract with third parties for access to tissue samples.

Under standard clinical practice, tumor biopsies removed from patients are preserved and stored in formalin-fixed paraffin embedded, or FFPE, format, and liquid biopsies are taken with a blood draw and stored in blood collection tubes. In order to add additional indications to our IVD products, if approved, we will need to secure access to these FFPE tumor biopsy and liquid biopsy samples, as well as information pertaining to the clinical outcomes of the patients from which they were derived for IVD development activities. Others compete with us for access to these samples. Additionally, the process of negotiating access to samples is lengthy because it typically involves numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters. We have in the past and may in the future be unable to negotiate access to tissue samples on a timely basis or on commercially reasonable terms, or at all. If we are unable to obtain access to these samples, or if other laboratories or competitors secure access to these samples before us, our ability to research, develop and commercialize future IVD products will be limited or delayed.

Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests.

Genetic testing has raised ethical, legal and social issues regarding privacy rights and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genomic tests even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests, either of which could have an adverse effect on our business, financial condition or results of operations.

We rely on third-party laboratories to perform portions of our biopharmaceutical testing services.

A portion of our biopharmaceutical testing services is performed by third-party laboratories. These third-party laboratories are subject to contractual obligations to perform these services for us, but are not otherwise under our control. We therefore do not control the capacity and quality control efforts of these third-party laboratories other than through our ability to enforce contractual obligations on volume and quality systems, and have no control over such laboratories' compliance with applicable legal and regulatory requirements. We also have no control over the timeliness of such laboratories' performance of their obligations to us, and the third-party laboratories that we have contracted with have in the past had, and occasionally continue to have, issues with delivering results to us or resolving issues with us within the time frames we expected or established in our contracts with them, which sometimes results in longer than expected turnaround times for, or negatively impacts the performance of, these tests and services. In the event of any adverse developments with these third-party laboratories or their ability to perform their obligations in a timely manner and in accordance with the standards that we and our customers expect, our ability to service customers may be delayed, interrupted or otherwise adversely affected, which could result in a loss of customers and harm to our reputation. Furthermore, when these issues arise, we have had to expend time, management's attention and other resources to address and remedy such issues.

We may not have sufficient alternative backup if one or more of the third-party laboratories that we contract with are unable to satisfy their obligations to us with sufficient performance, quality and timeliness. Any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at one or more of these third-party laboratories' facilities that causes a loss of capacity would heighten the risks that we face. Changes to or termination of agreements or inability to renew agreements with these third-party laboratories or enter into new agreements with other laboratories that are able to perform such portions of our service offerings could impair, delay or suspend our efforts to market and sell these services.

Our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- logistics and regulations associated with shipping samples, including infrastructure conditions, customs and transportation delays;
- limits on our ability to penetrate international markets if we do not to conduct our tests locally;
- natural disasters and outbreaks of disease, including the ongoing COVID-19 pandemic;
- political and economic instability, including wars such as the current conflict in Ukraine, terrorism and political unrest, boycotts, curtailment of trade, government sanctions and other business restrictions;
- inflationary pressures, such as those the global market is currently experiencing, which have and may increase costs for materials, supplies, and services; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our international operations and, consequently, our revenue and results of operations.

In addition, applicable export or import laws and regulations such as prohibitions on the export of samples imposed by countries outside of the United States, or international privacy or data restrictions that are different or more stringent than those of the United States, may require that we build additional laboratories or engage in joint ventures or other business partnerships in order to offer our tests internationally in the future. Any such restrictions would impair our ability to offer our tests in such countries and could have an adverse effect on our business, financial condition and results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

At December 31, 2021, our total gross deferred tax assets were \$640.5 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, our net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets are primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Some of our prior acquisitions have resulted in an ownership change, and we may experience ownership changes in the future. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, or other future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. In addition, the Tax Cuts and Jobs Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Also, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks related to government regulation

If the FDA regulates the tests we currently offer as LDTs as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.

We provide many of our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by CLIA, and state law, respectively).

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality system regulations, premarket clearance or premarket approval, and post-market controls). See Part I, Item 1. under the heading "Federal oversight of laboratory developed tests" for a description of applicable federal regulations, which is incorporated by reference herein.

If the FDA ultimately regulates certain LDTs, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition and results of operations.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

In addition, in November 2013, the FDA issued final guidance regarding the distribution of products labeled for research use only. Certain of the reagents and other products we use in our tests are labeled as research use only products. Certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

If we are unable to transition to the new European Union IVDR regulations, we could lose the ability to serve the European market.

The European Union transitions to a new regulation for in vitro diagnostic devices in May 2022, the In Vitro Diagnostic Regulation, or IVDR, which changes the regulatory status of a substantial number of IVDs. The percentage of devices requiring approval from a notified body is estimated to be shifting from 15% of devices under the current directive to between 70% and 90% of devices under the new regulation. Notified bodies must themselves be certified to the new regulation, and few have as of 2022. Consequently, notified bodies may have little or no capacity for new clients. LDTs are newly considered IVDs and subject to the IVDR, requiring approval from a notified body to be marketed. An amendment to the IVDR was adopted in December 2021, coming into force January 28, 2022, that extends the transition period for some provisions of the IVDR between one and six years. However, if we are unable to obtain a Conformité Européenne ("CE") Mark on our products under the European Directive 98/79/EC, or IVDD, before May 2022 or implement the provisions of the IVDR that have not been delayed, we will not be able to take advantage of the extension. Moreover, any significant changes to one of our tests after May 2022 may cause it to be subject to the new regulations. If we are unable to secure a notified body or complete registration in time for implementation of the new regulation, our existing tests cannot be marketed in Europe.

If we fail to comply with federal, state and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers, for our tests. We have current CLIA certifications to conduct our tests at our laboratories in California, Colorado, New Jersey, and Washington. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories.

We are also required to maintain in-state licenses to conduct testing in California, New Jersey and Washington. California, New Jersey and Washington laws establish standards for day-to-day operation of our clinical reference laboratories in those states, which include the training and skills required of personnel and quality control. Our Colorado laboratory is not required to maintain a state clinical laboratory license.

Several states require the licensure of out-of-state laboratories that accept specimens from those states. All our laboratories hold the required state laboratory licenses for California, Maryland, Pennsylvania, and Rhode Island, and all our laboratories, with the exception of Colorado, hold a New York State permit.

In addition to having laboratory licenses in New York, our clinical reference laboratories are approved on test-specific bases for the tests they run as LDTs by the New York State Department of Health, or NYDOH, for tests offered to patients in New York. Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of samples necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays.

In order to eventually market certain of our current or future products and services in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding quality, safety, performance and efficacy. In addition, clinical trials or clinical investigations conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory clearance, authorization or approval in one country does not guarantee regulatory clearance, authorization or approval in any other country. For example, the performance characteristics of certain of our products and services may need to be validated separately in specific ethnic and genetic populations. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory clearance, authorization or approval could result in difficulties and costs for us and our collaborators and require additional preclinical studies, clinical trials or clinical investigations which could be costly and time-consuming. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of certain of our products and services in those countries. The foreign regulatory clearance, authorization or approval process involves all of the risks and uncertainties associated with FDA clearance, authorization or approval. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products and services will be unrealized.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, cancellation of the laboratory's approval to receive Medicare and Medicaid payment for its services, exclusion from some healthcare systems' programs, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certifications, a state or foreign license, or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

The College of American Pathologists, or CAP, maintains a clinical laboratory accreditation program. CAP asserts that its program is "designed to go well beyond regulatory compliance" and helps laboratories achieve the highest standards of excellence to positively impact patient care. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. We have CAP accreditations for our laboratories. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

We may not be able to obtain regulatory clearance or approval of our IVD products, or even if approved, such products may not be approved for guideline inclusion, which could adversely affect our ability to realize the intended benefits of our acquisition of ArcherDX.

A significant portion of our therapy selection and personalized cancer monitoring commercial strategy, including for PCM, relies on receiving regulatory approvals with guideline inclusion to strengthen our position in establishing coverage and reimbursement of our IVD products with both public and private payers. If we do not receive such regulatory approvals in a timely manner or at all, or we are not successful in obtaining such guideline inclusion, we may not be able to commercialize our IVD products. Additionally, third-party payers may be unwilling to provide sufficient coverage and reimbursement for these products necessary for hospitals and other healthcare providers to adopt our solutions as part of their oncological treatment strategy. We have also focused our efforts on the development of PCM for FDA clearance and approval as a prognostic device for predicting recurrence of a primary cancer after initial treatment, which can include surgery alone or surgery plus adjuvant therapy.

Moreover, development of the data necessary to obtain regulatory clearance and/or approval of an IVD is time-consuming and carries with it the risk of not yielding the desired results. The performance achieved in published studies may not be repeated in later studies that may be required to obtain FDA clearance and/or approval or regulatory approvals in foreign jurisdictions. Limited results from earlier-stage verification studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over longer periods of time. Unfavorable results from ongoing preclinical and clinical studies could result in delays, modifications or abandonment of ongoing analytical or future clinical studies, or abandonment of a product development program, or may delay, limit or prevent regulatory approvals or clearances or commercialization of our product candidates, any of which may materially impact our ability to realize the expected benefits of our acquisition of ArcherDX.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- HIPAA, which establishes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions;
- amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators and expand vicarious liability, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- the GDPR, which imposes strict privacy and security requirements on controllers and processors of personal data, including enhanced protections for “special categories” of personal data, including sensitive information such as health and genetic information of data subjects;
- the CCPA, which, among other things, regulates how subject businesses may collect, use, and disclose the personal information of consumers who reside in California, affords rights to consumers that they may exercise against businesses that collect their information, and requires implementation of reasonable security measures to safeguard personal information of California consumers;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or recommend purchasing, leasing or ordering, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;
- The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and reaches beyond federal health care programs, to include private insurance;
- the federal physician self-referral law, known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity unless an exception applies, and prohibits an entity from billing for designated health services furnished pursuant to a prohibited referral;

- the federal false claims law, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the HIPAA fraud and abuse provisions, which create new federal criminal statutes that prohibit, among other things, defrauding health care benefit programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;
- the 21st Century Cures Act information blocking prohibition, which prohibits covered actors from engaging in certain practices that are likely to interfere with the access, exchange, or use of electronic health information;
- the Physician Payments Sunshine Act and similar state laws that require reporting of certain payments and other transfers of value made by applicable manufacturers, directly or indirectly, to or on behalf of covered recipients including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- state laws that limit or prohibit the provision of certain payments and other transfers of value to certain covered healthcare providers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payers; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance may also be subject to governmental review. The growth of our business and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. We recently received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting that we produce certain documents regarding our sponsored testing programs. We are in the process of responding to the subpoena and are cooperating fully with the investigation. Although we remain committed to compliance with all applicable laws and regulations, we cannot predict the outcome of this investigation or any other requests or investigations that may arise in the future regarding these or other subject matters. Any action brought against us for violation of the above-referenced or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in Federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Healthcare policy changes, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition, results of operations and cash flows.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Policy changes or implementation of new health care legislation could result in significant changes to health care systems. In the United States, this could include potential modification or repeal of all or parts of the Affordable Care Act.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, as amended, and its implementing regulations, clinical laboratories must report to CMS private payer rates beginning in 2017, and then in 2023 and every three years thereafter for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests and every year for advanced diagnostic laboratory tests.

We have not sought "advanced diagnostic laboratory test" status for our tests, but in the event that we seek designation for one or more of our tests as an advanced diagnostic laboratory test and the tests are determined by CMS to meet these criteria or new criteria developed by CMS, we would be required to report private payer data for those tests annually. Otherwise, we will be required to report private payer rates for our tests on an every three years basis starting in 2023. Laboratories that fail to timely report the required payment information may be subject to substantial civil money penalties.

See Part I, Item 1. under the heading "Reimbursement" for a description of how public and private payors pay for our products and services, which is incorporated by reference herein. Changes in these payments and the methodologies used to determine payment amounts could have a significant impact on our financial condition, results of operations and cash flows.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. For instance, the payment reductions imposed by the Affordable Care Act and the expansion of the federal and state governments' role in the U.S. healthcare industry as well as changes to the reimbursement amounts paid by payers for our tests and future tests or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Notably, Congress enacted legislation in 2017 that eliminated the Affordable Care Act's "individual mandate" beginning in 2019, which may significantly impact the number of covered lives participating in exchange plans. Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would increase our billing and collecting costs and decrease our revenue. Further, it is possible that additional governmental action be taken in response to the COVID-19 pandemic.

If we use hazardous materials in a manner that causes injury, we could be liable for resulting damages.

Our activities currently require the use of hazardous chemicals and biological material. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. In 2018, we decommissioned our laboratory in Massachusetts; however, we could be held liable for any damages resulting from our prior use of hazardous chemicals and biological materials at this facility. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

We could be adversely affected by violations of the FCPA and other worldwide anti-bribery laws.

We are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are increasing our direct sales and operations personnel outside the United States, in which we have limited experience. We use a limited number of independent distributors to sell our tests internationally, which requires a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to

similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

Risks related to our intellectual property

One of our competitors has alleged that our Anchored Multiplex PCR, or AMP, chemistry and products using AMP are infringing on its intellectual property, and we may be required to redesign the technology, obtain a license, cease using the AMP chemistry altogether and/or pay significant damages, among other consequences, any of which would have a material adverse effect on our business as well as our financial condition and results of operations, and the intended benefits of our acquisition of ArcherDX.

ArcherDX's AMP chemistry underlies all of its RUO products and is also the foundation of our therapy selection IVDs and PCM. One of ArcherDX's competitors, Natera, Inc., or Natera, has filed complaints against ArcherDX, Invitae and Genosity alleging that our products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe certain patents. A description of this ongoing litigation is provided in Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

If any of our products or our use of AMP chemistry is found to infringe any of Natera's patents, we could be required to redesign our technology or obtain a license from Natera to continue developing, manufacturing, marketing, selling and commercializing AMP and related products. However, we may not be successful in the redesign of its technology or able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving Natera and other third parties the right to use the same technologies licensed to us, and Natera could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to permanently cease developing, manufacturing, marketing and commercializing our products that are found to be infringing. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed Natera's asserted patents. Even if we were ultimately to prevail, litigation with Natera could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We cannot reasonably estimate the final outcome, including any potential liability or any range of potential future charges associated with these litigations. However, any finding of infringement by us of Natera's asserted patents could have a material adverse effect on our business and the benefits we expected to achieve through our acquisition of ArcherDX, as well as our financial condition and results of operations.

Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation will require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price.

Our commercial success will depend in part on our avoiding infringement of patents and proprietary rights of third parties, including for example the intellectual property rights of competitors. As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests, and enter new markets, competitors might claim that our tests infringe or misappropriate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. Our activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. For example, as discussed in the preceding risk factor, we are currently engaged in litigation with a competitor of ArcherDX alleging infringement. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We may be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, regardless of merit, could cause us to incur substantial expenses and be a substantial diversion of our employee resources. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our business and stock price. In the event of a successful claim of

infringement against us by a third party, we may have to (1) pay substantial damages, possibly including treble damages and attorneys' fees if we are found to have willfully infringed patents; (2) obtain one or more licenses, which may not be available on commercially reasonable terms (if at all); (3) pay royalties; and/or (4) redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, all of which could have a material adverse impact on our cash position and business and financial condition.

If licenses to third-party intellectual property rights are or become required for us to engage in our business, we may be unable to obtain them at a reasonable cost, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in the introduction of tests while we attempt to develop alternatives. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing tests, which could materially affect our ability to grow and thus adversely affect our business and financial condition.

Developments in patent law could have a negative impact on our business.

Although we view current U.S. Supreme Court precedent to be aligned with our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts (such as patient genetic data) and an understanding of that fact's implications (such as a patient's risk of disease associated with certain genetic variations) should not be patentable, it is possible that subsequent determinations by the U.S. Supreme Court or other federal courts could limit, alter or potentially overrule current law. Moreover, from time to time the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office, or USPTO, may change the standards of patentability, and any such changes could run contrary to, or otherwise be inconsistent with, our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts and an understanding of that fact's implications should not be patentable, which could result in third parties newly claiming that our business practices infringe patents drawn from categories of patents which we currently view to be invalid as directed to unpatentable subject matter. For example, the U.S. Senate Judiciary Committee, Subcommittee on Intellectual Property held hearings in 2019 regarding a legislative proposal that would overrule current U.S. Supreme Court precedent concerning the scope of patentable subject matter. Our President and Chief Executive Officer, Sean George, appeared before this subcommittee. If such proposal were to be formulated as a bill and enacted into law, there could be an increase in third-party claims to patent rights over correlations between patient genetic data and its interpretation and such third parties may assert that our business practices infringe some of those resulting patent rights.

Our inability to effectively protect our proprietary technologies, including the confidentiality of our trade secrets, could harm our competitive position.

We currently rely upon trade secret protection and copyright, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, and to a limited extent patent protection, to protect our confidential and proprietary information. Although our competitors have utilized and are expected to continue utilizing similar methods and have aggregated and are expected to continue to aggregate similar databases of genetic testing information, our success will depend upon our ability to develop proprietary methods and databases and to defend any advantages afforded to us by such methods and databases relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our methods and databases and thereby erode any competitive advantages we may have.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. In this regard, we have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, we expect that potential patent coverage we may obtain will not be sufficient to prevent substantial competition. In this regard, we believe it is probable that others will independently develop similar or alternative technologies or design around those technologies for which we may obtain patent protection. In addition, any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. Questions as to inventorship or ownership may also arise. Any finding that our patents or applications are unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, which would be expensive, and, if we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel.

We expect to rely primarily upon trade secrets and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. Among other things, we seek to protect our trade secrets and confidential information by entering into confidentiality agreements with employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees and consultants will provide meaningful protection for our trade secrets and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Accordingly, there also can be no assurance that our trade secrets will not otherwise become known or be independently developed by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks related to being a public company

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the Securities and Exchange Commission, or SEC, and the New York Stock Exchange, or NYSE, impose a number of requirements on public companies, including with respect to corporate governance practices. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In addition, the Dodd-Frank Wall Street Reform

and Consumer Protection Act, or the Dodd-Frank Act, enacted in 2010, includes significant corporate governance and executive-compensation-related provisions. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. If these requirements divert the attention of our management and personnel from other aspects of our business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, these rules and regulations applicable to public companies substantially increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time consuming and costly. It may also be more expensive for us to obtain director and officer liability insurance.

If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

We are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have compiled the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. As we acquire companies, we will need to establish adequate controls and integrate them into our internal control system. We need to maintain and enhance these processes and controls as we grow and we have required, and may continue to require, additional personnel and resources to do so.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal controls, our management will be unable to conclude that our internal control over financial reporting is effective. Our independent registered public accounting firm is required to issue an attestation report on the effectiveness of our internal control over financial reporting every fiscal year. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in the restatement of our financial results in the future.

Risks related to our indebtedness

The terms of our credit agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In October 2020, we entered into a credit agreement with Perceptive Credit Holdings II, LP, pursuant to which we borrowed an aggregate principal amount of \$135.0 million, or the 2020 Term Loan. The 2020 Term Loan is secured by a first priority lien on all of our and our subsidiaries' assets (including our intellectual property) and is guaranteed by our subsidiaries, in each case, excluding certain excluded assets and immaterial subsidiaries. If the 2020 Term Loan is prepaid, we may be required to pay a prepayment fee of up to 6% and a make-whole fee, in each case depending on when the prepayment is made. Our 2020 Term Loan bears interest at an annual rate equal to three-month London Interbank Offered Rates, or LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75% and is therefore sensitive to changes in interest rates. If three-month LIBOR can no longer be determined or if the applicable governmental authority ceases to supervise or sanction such rates, then we will endeavor to agree with the administrative agent, an alternate rate of interest that gives due consideration to the then prevailing market convention for determining interest for comparable loans in the United States; provided that until such alternative rate of interest is agreed, the 2020 Term Loan shall bear interest at the Wall Street Journal Prime Rate. We cannot predict what the impact of any such alternative rate would be to our interest expense. However, the discontinuation, reform, or replacement of LIBOR or any other benchmark rates may result in fluctuating interest rates that may have a negative impact on our interest expense and cash flows. Furthermore, we cannot predict or quantify the time, effort and cost required to transition to the use of new benchmark rates, including with respect to negotiating and implementing any necessary changes to the 2020 Term Loan, and implementing changes to our systems and processes.

The credit agreement restricts our ability to pursue certain mergers, acquisitions, amalgamations or consolidations, other than permitted acquisitions, that we may believe to be in our best interest. In addition, the credit agreement contains financial covenants that require us to maintain a minimum cash balance and minimum quarterly revenue levels. If we default under the credit agreement, the lender will be able to declare all obligations immediately due and payable, including prepayment fees and other obligations. The lender could declare an event of default under the credit agreement upon the occurrence of any event that it interprets as a material adverse change or material adverse effect, each as defined under the credit agreement. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We have a large amount of debt, servicing our debt requires a significant amount of cash, and our debt service obligations may prevent us from taking actions that we would otherwise consider to be in our best interests.

In September 2019, we issued \$350.0 million aggregate principal amount of our convertible senior notes due 2024 in a private placement, in October 2020 we entered into our credit agreement and borrowed \$135.0 million through the 2020 Term Loan and in April 2021 we issued \$1,150.0 million on aggregate principal amount of our convertible senior notes due 2028 in a private placement.

Our substantial leverage could have significant negative consequences for our future operations, including:

- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financial for working capital, acquisitions, research and development expenditures, and general corporate purposes;
- requiring the dedication of a substantial portion of our expected cash flow or our existing cash to service our indebtedness, thereby reducing the amount of our cash available for other purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; or
- placing us at a possible competitive disadvantage compared to less leveraged competitors and competitors that have better access to capital resources.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to settle conversions of our convertible senior notes in cash or to repurchase the notes upon a fundamental change, and our current credit agreement contains and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the notes.

Holders of our convertible senior notes have the right to require us to repurchase all or any portion of their notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. The repurchase price for our convertible senior notes due 2028 will also include unpaid interest on those notes to the maturity date. In addition, upon conversion of the notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the notes being converted. However, we only have limited ability to make those cash payments under our credit agreement and, even if the credit agreement limitations are no longer in effect, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of notes surrendered therefor or notes being converted. In addition, our ability to repurchase the notes or to pay cash upon conversions of the notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the indentures governing the notes or to pay any cash payable on future conversions of the notes as required by the indentures would constitute a default under

the relevant indenture. A default under an indenture or the occurrence of the fundamental change itself could also lead to a default under our credit agreement and any agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and to repay or repurchase our convertible senior notes.

The conditional conversion feature of our convertible senior notes due 2024, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of our convertible senior notes due 2024 is triggered, holders of such notes will be entitled to convert the notes at any time during specified periods at their option. If one or more holders elect to convert their notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

General risk factors

Our stock price is volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

The trading price of our common stock is volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated fluctuations in our operating results;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our stock;
- our focus on long-term goals over short-term results;
- the level of short interest in our stock, and the effect of short sellers on the price of our stock;
- the timing and magnitude of our investments in the growth of our business;
- actual or anticipated changes in regulatory oversight of our business;
- additions or departures of key management or other personnel;
- disputes or other developments related to our intellectual property or other proprietary rights, including litigation;
- changes in reimbursement by current or potential payers;
- general economic and market conditions; and
- issuances of significant amounts of our common stock.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. The closing price of our common stock on NYSE ranged from \$9.68 to \$53.62 between February 1, 2021 through January 31, 2022. Broad market and industry factors, including the COVID-19 pandemic, as well as general economic, political and geopolitical, and market conditions such as recessions, wars, elections, interest rate changes, or cost inflation, may seriously affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock, change their price targets, issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, the terms of our credit agreement restrict our ability to pay dividends. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 20,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our chair of the board or our chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum; and
- require a super-majority of votes to amend certain of the above-mentioned provisions as well as to amend our bylaws generally.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;

- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law; or
- any action asserting a claim against us governed by the internal affairs doctrine.

Section 27 of the Securities Exchange Act of 1934, or Exchange Act, creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 22 of the Securities Act of 1933, or Securities Act, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of December 31, 2021, we had outstanding 228.1 million shares of our common stock, options to purchase 3.0 million shares of our common stock (of which 2.6 million were exercisable as of that date) and outstanding restricted stock units, or RSUs, representing 16.2 million shares of our common stock (which includes an estimated number of RSUs, subject to certain employees' continued service with us, or time-based RSUs, and RSUs that are performance based RSUs, or PRSUs, granted in connection with an acquisition). The foregoing does not include 10.2 million shares of common stock that may be issuable in connection with indemnification hold-backs and contingent consideration related to our acquisitions, shares that may be issuable in the future in connection with the convertible senior notes, or shares issuable pursuant to our May 2021 sales agreement with Cowen and Company, LLC under which we may offer and sell from time to time at our sole discretion up to \$400 million of shares of our common stock. In addition, as of December 31, 2021, 10.2 million and 2.1 million shares of common stock are available for future issuance under our 2015 Stock Incentive Plan and Employee Stock Purchase Plan, respectively, and as of January 1, 2022, 9.1 million and 2.3 million additional shares of common stock became available for future issuance under our 2015 Stock Incentive Plan and our Employee Stock Purchase Plan, respectively. The sale or the availability for sale of a large number of shares of our common stock in the public market could cause the price of our common stock to decline.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Our headquarters and main production facility is located in San Francisco, California, where we currently lease and occupy approximately 103,000 square feet of laboratory and office space. The lease for this facility expires in July 2026 and we may renew the lease for an additional ten years.

We also lease approximately 585,000 square feet of additional office and laboratory space domestically in California, Colorado, Massachusetts, New Jersey, New York, North Carolina and Washington, and internationally in Australia, Belgium and Israel.

We believe that our facilities are adequate for our current needs and that additional space will be available on commercially reasonable terms if required.

ITEM 3. Legal Proceedings

For a discussion of legal matters as of December 31, 2021, see Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report, which is incorporated into this item by reference.

ITEM 4. Mine Safety Disclosure

Not applicable.

PART II

ITEM 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock has been publicly traded on the New York Stock Exchange under the symbol “NVTA” since February 12, 2015. Prior to that time, there was no public market for our common stock.

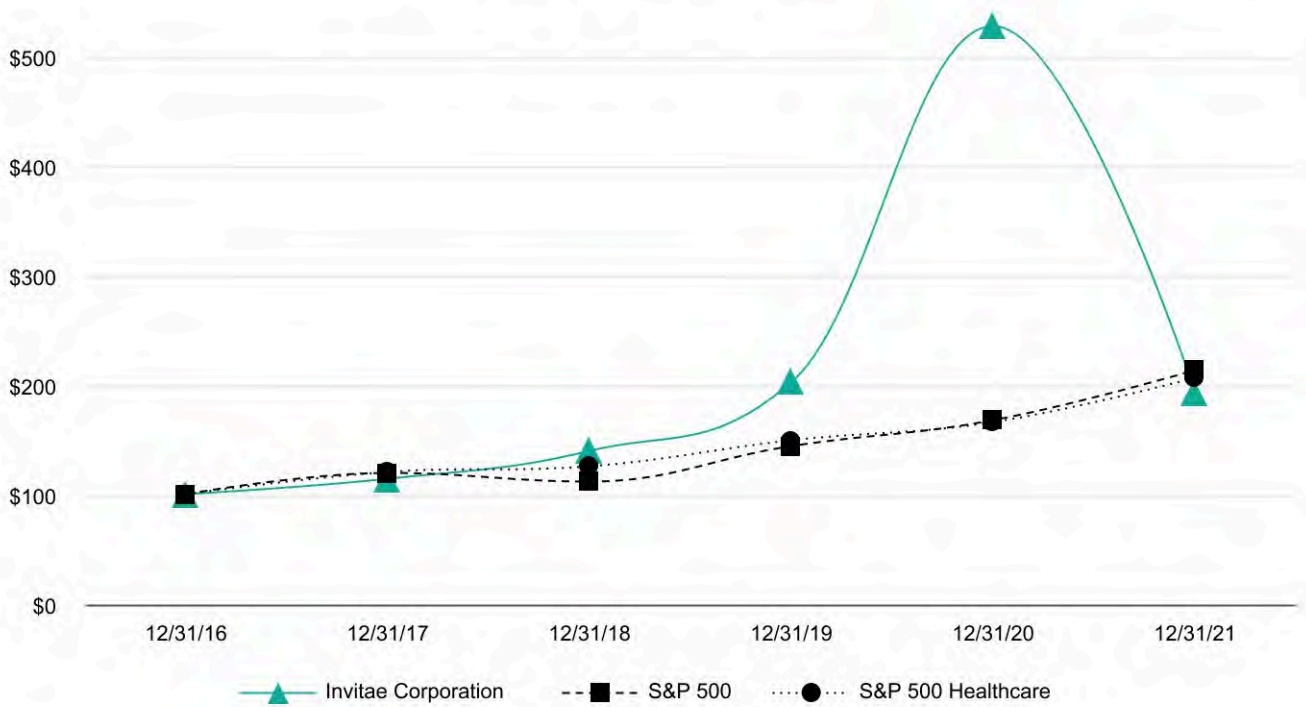
As of February 25, 2022, there were 297 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. In addition, the terms of the credit agreement restrict our ability to pay dividends. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements and general business conditions and other factors that our board of directors may deem relevant.

Stock performance graph

The following information shall not be deemed to be soliciting material or to be filed with the SEC, or subject to Regulations 14A or 14C under the Securities Exchange Act of 1934, or Exchange Act, or to the liabilities of Section 18 of the Exchange Act nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

Comparison of Historical Cumulative Total Return Among Invitae Corporation, the S&P 500 Index and the S&P 500 Healthcare Index (*)



(*) The above graph shows the cumulative total stockholder return of an investment of \$100 in cash on December 31, 2016 through December 31, 2021 for: (i) our common stock; (ii) the S&P 500 Index; and (iii) the S&P 500 Healthcare Index. All values assume reinvestment of the full amount of all dividends. The comparisons in the table are not intended to be forecasts or indicative of future stockholder returns.

	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021
Invitae Corporation	\$ 100.00	\$ 114.36	\$ 139.29	\$ 203.15	\$ 526.57	\$ 192.32
S&P 500	\$ 100.00	\$ 119.42	\$ 111.97	\$ 144.31	\$ 167.77	\$ 212.89
S&P 500 Healthcare Index	\$ 100.00	\$ 120.00	\$ 125.63	\$ 149.10	\$ 166.14	\$ 206.29

ITEM 6. [Reserved]

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Historic results are not necessarily indicative of future results.

Business overview

We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, personalized oncology, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets and businesses, which expanded our suite of genome management offerings and established a broader entry into key genomics markets. We are building a platform to harness genetics on a global scale to diagnose more patients correctly, earlier and bring therapies to market faster. Our genome management offerings will provide information services to the patient that are intended to enhance the customer experience through personalized insights, technology-enabled services and network connections that inform genetic healthcare throughout life.

In 2021, we completed the acquisitions of Reference Genomics, Inc. d/b/a One Codex, or One Codex, Genosity, Inc., or Genosity, Medneon LLC, or Medneon, Ciitizen Corporation, or Ciitizen, and Stratify Genomics Inc., or Stratify. One Codex is a data platform for applied microbial genomics. Its acquisition adds capabilities across microbiome and infectious disease testing capabilities and allows us to deliver a high-quality, low-cost, end-to-end metagenomics product (sequencing and results) and enables the development of future offerings in infectious disease, preterm birth and wellness.

Genosity is a genomics and laboratory services company offering software and laboratory solutions that enable the deployment of complex sequencing-based cancer testing. The acquisition brings Genosity's specialized capabilities onto the Invitae platform to accelerate the time to market and decentralization of Invitae's personalized oncology offerings, including somatic and germline offerings used in screening, therapy selection and personalized cancer monitoring.

The Medneon digital platform combines artificial intelligence and human insights with actionable information regarding an individual's cancer risk to inform precision prevention and management over time at the point-of-care or through telemedicine.

Ciitizen is a patient-centric consumer health tech company working to build a global platform to help patients collect, organize, store and share their medical records digitally.

Stratify is a cancer risk stratification company for the general population offering a prostate risk score product and is dedicated to advancing the knowledge of genetic predisposition to cancer and other diseases so that practitioners can screen more effectively and efficiently.

In October 2020, we completed the acquisition of ArcherDX, Inc., or ArcherDX, a genomics company democratizing precision oncology by offering a suite of products and services that are accurate, personal, actionable and easy to use in local settings, thereby empowering clinicians to control the sample, data, patient care and economics. As part of the acquisition, we agreed to pay contingent consideration based on the achievement of five post-closing development, regulatory and revenue milestones. The first milestone was achieved in November 2020, and in June 2021, three additional milestones were achieved or deemed to be achieved. The remaining milestone is based upon receiving FDA clearance or approval of a therapy selection IVD, which per the terms of the acquisition agreement, must be completed by March 31, 2022, subject to certain extensions. Based on the current development timeline, during the year ended December 31, 2021, we determined that this milestone will not be met by the required achievement date per the acquisition agreement, although we expect to receive FDA clearance or approval at a later date.

We have experienced rapid growth. For the years ended December 31, 2021, 2020 and 2019, our revenue was \$460.4 million, \$279.6 million and \$216.8 million, respectively, and we incurred net losses of \$379.0 million, \$602.2 million and \$242.0 million, respectively. At December 31, 2021, our accumulated deficit was \$1.7 billion. To meet the demands of scaling our business, we increased our number of employees to approximately 3,000 at December 31, 2021 from approximately 2,100 at December 31, 2020. Our sales force grew to approximately 330 at December 31, 2021 from approximately 300 at December 31, 2020. We expect headcount will continue to increase as we add staff to support anticipated growth.

Sales of our tests have grown significantly. In 2021, 2020 and 2019, we generated 1,169,000, 659,000 and 469,000 billable units, respectively. We calculate volume using billable units, which are billable events that include individual test reports released and individual reactions shipped. We refer to the set of reagents needed to perform an

NGS test as a "reaction." Through December 31, 2021, approximately 57% of the billable volume generated were billable to patients, biopharmaceutical partners and other business-to-business customers (e.g., hospitals, clinics, medical centers), and the remainder were billable to government and private insurance payers. Many of the gene tests on our assays are reimbursable by health insurance companies. However, when we do not have reimbursement policies or contracts with private insurers, our claims for reimbursement may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. Even if we are successful in achieving reimbursement, we may be paid at lower rates than if we were under contract with the third-party payer. When there is not a contracted rate for reimbursement, there is typically a greater payment requirement from the patient that may result in further delay in payment for these tests.

We expect to incur operating losses for the near term as we continue to invest in our business to achieve our revenue growth objectives, including expansion of our platform to capture the broad potential of genetics across healthcare and expansion into new laboratory and production facilities, and expect we will need to raise additional capital in order to fund our operations. If we are unable to achieve these objectives and successfully manage our costs, we may not be able to achieve profitability in the near term or at all.

We believe that the keys to our future growth will be to increase billable volume, achieve broad reimbursement coverage for our tests from third-party payers and increase the amount we receive from other types of payers, advance digital health solutions and data services, drive down the price for genetic analysis and interpretation, reduce the costs associated with performing our genetic tests, steadily increase the amount of genetic content we offer, consistently improve the client experience, drive physician and patient utilization of our website for ordering and delivery of results and increase the number of strategic partners working with us to add value for our clients. We also believe that providing a unique genetic testing platform that is agnostic to stage of life or disease category will deliver unique benefits to customers, payers and other institutions that are seeking to make genetic information a standard element of healthcare decisions in the future.

Impact of COVID-19

Our daily test volumes have recovered from the low in March 2020, although the ongoing COVID-19 pandemic continues to impact our business operations and practices. While we expect it may continue to impact our business, we experienced limited disruption during 2021. We have reviewed and adjusted, when necessary, for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

In response to the pandemic, we have implemented measures to protect the health of all of our employees during this time with additional measures in place to better protect our on-site lab production and support teams. Our production facilities currently remain fully operational. While we have not experienced significant disruption in our supply chain, we have experienced supply delays as a result of the COVID-19 pandemic and have also had to obtain supplies from new suppliers. Although we do not yet know the ongoing impact COVID-19 will have on our supply chain, we have increased our inventory on hand to respond to potential future disruptions that may occur.

Many announced healthcare guidelines call for a shift of regular physician visits and healthcare delivery activities to remote/telehealth formats. This is particularly important for patients who, despite the fall-out from COVID-19, continue to be diagnosed with critical diseases, like cancer, and for women who are pregnant or are trying to conceive. We believe our investments in new access platforms and technologies has and will continue to position us well to provide a range of testing to clinicians and patients using a "clinical care from afar" model. An example is our rollout in April 2020 of our Gia telehealth platform, which expands access to remote interaction between patients and clinicians as well as direct ordering of genetic tests.

Given the unknown duration and extent of COVID-19's impact on our business, and the healthcare system in general, we continue to monitor evolving market conditions and have pivoted our focus and investments on the commercial execution of workflows that support remote ordering, online support and telehealth. Approximately 8% of our workforce as of March 2020 was impacted by a reduction in force in April 2020 in an initiative to manage costs and cash burn, which resulted in one-time costs in the second quarter of 2020 of \$3.8 million. In addition, effective May 2020, we reduced the salaries of our named executive officers by approximately 20%, which ceased as of January 2021.

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was signed into law as a stimulus bill intended to bolster the economy, among other things, and provide assistance to qualifying businesses and individuals. The CARES Act included an infusion of funds into the healthcare system. In April 2020, we received \$3.8 million as a part of this initiative, and in January 2021, we received an additional \$2.3 million. These payments were recognized as other income, net in our consolidated statements of operations in the periods received. At this time, we are not certain of the availability, extent or impact of any future relief provided under the CARES Act.

Factors affecting our performance

Number of billable units

Our centralized test revenue is tied to the number of tests which we bill third-party payers, biopharmaceutical partners, other business-to-business customers (e.g., hospitals, clinics, medical centers), or patients. Our decentralized product revenue is based upon the number of individual reactions we ship biopharmaceutical partners and other business-to-business customers. We refer to the set of reagents needed to perform an NGS test as a "reaction," and we refer to billable events that include individual test reports released and individual reactions shipped as billable units. We typically bill for our services following delivery of the billable report derived from testing samples and interpreting the results. For units manufactured for use by customers in distributed facilities, we typically bill customers upon shipment of those units. Test orders are placed under signed requisitions or contractual agreements, as we often enter into contracts with biopharmaceutical partners, other business-to-business customers and insurance companies. We incur the expenses associated with a unit in the period in which the unit is processed regardless of when payment is received with respect to that unit. We believe the number of billable units in any period is an important indicator of the growth in our testing business, and with time, this will translate into the number of customers accessing our platform.

Number and size of research and commercial partnerships

Pharma development services revenue, which we recognize within other revenue in our consolidated statements of operations, is generated primarily from services provided to biopharmaceutical companies and other partners and is related to companion diagnostic development, clinical research, and clinical trial services across the research, development, and commercialization phases of collaborations. The result of these relationships may include the development of new targeted companion diagnostics, which underscore and expand the need for genetic testing and in some cases may lead to intellectual property and/or revenue sharing opportunities with third-party partners.

In addition to research partnerships, we also seek to grow the number of biopharmaceutical partners and other business-to-business customers for whom we provide testing technologies, analysis, supplies and expertise to institutions that provide independent testing services to customers in their respective regions.

Success obtaining and maintaining reimbursement

Our ability to increase volume and revenue will depend in part on our success achieving broad reimbursement coverage and laboratory service contracts for our tests from third-party payers and agreements with institutions and partners. Reimbursement may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary and cost-effective, as well as whether we are in contract, where we get paid more consistently and at higher rates. Because each payer makes its own decision as to whether to establish a policy or enter into a contract to reimburse for our testing services and specific tests, seeking these approvals is a time-consuming and costly process. In addition, clinicians and patients may decide not to order our tests if the cost of the test is not covered by insurance. Because we require an ordering physician to requisition a test, our revenue growth also depends on our ability to successfully promote the adoption of our testing services and expand our base of ordering clinicians. We believe that establishing coverage and obtaining contracts from third-party payers is an important factor in gaining adoption by ordering clinicians. Our arrangements for laboratory services with payers cover approximately 322 million lives, comprised of Medicare, national commercial health plans, and Medicaid in most states, including California (Medi-Cal), our home state.

Ability to lower the costs associated with performing our tests

Reducing the costs associated with performing our genetic tests is both a focus and a strategic objective of ours. Over the long term, we will need to reduce the cost of raw materials by improving the output efficiency of our assays and laboratory processes, modifying our platform-agnostic assays and laboratory processes to use materials and technologies that provide equal or greater quality at lower cost, improve how we manage our materials, port some tests onto a next generation sequencing platform and negotiate favorable terms for our materials purchases. We also intend to continue to design and implement hardware and software tools that are designed to reduce personnel-related costs for both laboratory and clinical operations/medical interpretation by increasing personnel efficiency and thus lowering labor costs per test. Finally, we plan to reduce the cost of providing test equipment and software to laboratories and other facilities in the United States and internationally. Those efforts are designed to enable more rapid expansion of genetic testing and patient access, enlarging our geographic footprint outside the United States while achieving lower costs.

Ability to expand our genetic content and create new pathways to test

We believe our focus on reducing the average cost per test will have a countervailing force — increasing the number of tests we offer, the content of each test and the means to connect our testing services with patients and physicians. We intend to continue to expand our test menus by steadily releasing additional genetic content for affordable prices, ultimately leading to affordable whole genome services. The breadth and flexibility of our offering will be a critical factor in our ability to address new markets, including internationally, for genetic testing services. Both of these, in conjunction with our continued focus on strategic partnerships, will be important to our ability to continue to grow the volume of billable tests we deliver. We have and will continue to identify new ways to connect our testing services and information to patients. These include direct patient outreach and ordering capacity, the use of automated assistants for physician customers to improve the ease of ordering and processing genetic tests and programs designed to reach underserved patient populations with genetic testing.

Investment in our business and timing of expenses

We plan to continue to invest in our genetic testing and information management business. We deploy state-of-the-art technologies in our genetic testing services, and we intend to continue to scale our infrastructure, including our testing capacity and capabilities as well as our information systems. We plan to do this through the acquisition of assets and businesses and expansion of our workforce and facilities, such as our new laboratory and production facility in North Carolina and the genomic laboratory space added through the acquisition of Genosity, which we expect to support our continued growth by significantly expanding our testing capacity. We also expect to incur software development costs as we seek to further automate our laboratory processes and our genetic interpretation and report sign-out procedures, scale our customer service capabilities to improve our customers' experience, and expand the functionality of our website. We also expect to incur costs as we seek to provide the testing equipment and software necessary to enable decentralized genetic and genomic testing in the United States and internationally. We will incur costs related to marketing and branding as we spread our initiatives beyond our current customer base and focus on providing access to customers through our website. We plan to hire additional personnel as necessary to support anticipated growth, including software engineers, sales and marketing personnel, billing personnel, research and development personnel, medical specialists, biostatisticians and geneticists. We will also incur additional costs related to the expansion of our production facilities to accommodate growth and as we expand domestically and internationally, including increased operating costs and capital expenditures related to the buildout of our new laboratory and production facility in North Carolina. In addition, we will incur ongoing expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter as we focus on building out different aspects of our business.

How we recognize revenue

We generally recognize revenue on an accrual basis, which is when a customer obtains control of the promised goods or services, typically a test report, or upon shipment of our precision oncology products. Accrual amounts recognized are based on estimates of the consideration that we expect to receive, and such estimates are adjusted and subsequently recorded until fully settled. Changes to such estimates may increase or decrease revenue recognized in future periods. Revenue from our tests may not be equal to billed amounts due to a number of factors, including differences in reimbursement rates, the amounts of patient payments, the existence of secondary payers and claim denials. Some test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with biopharmaceutical partners, other business-to-business customers and insurance companies that include pricing provisions under which such tests are billed.

Pharma development service revenues are generated primarily from custom assay design services, sample processing activities and consultative inputs, which is separate from revenue generated by any related or unrelated product component. Revenue is recognized as samples are processed or scope of work is completed based on contracted agreements with those biopharmaceutical customer companies.

Under these collaborations we also generate revenue from achievement of milestones, provision of on-going support, and related pass-through costs and fees. We generally have distinct performance obligations for development milestones related to our development of a companion diagnostic device. We use a cost plus a margin approach to estimate the standalone value of our companion diagnostic development service performance obligations. Revenue is recognized over time using input methods based on our assessments of performance completed to date toward each milestone.

Financial overview

Revenue

We primarily generate revenue from testing services and sales of distributed precision oncology products. Customers are typically billed upon delivery of test results or shipment of products. We also generate revenue from development agreements, access to data, data analytics and other related services provided for biopharmaceutical partners and other parties. Our ability to increase our revenue will depend on our ability to increase our market penetration, obtain FDA and other international regulatory authority approvals on future products and services offerings, obtain contracted reimbursement coverage from third-party payers, and grow our relationships with biopharmaceutical customers.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering our products and services and includes expenses for materials and supplies, personnel-related costs, freight, costs for lab services, genetic interpretation and clinical trial support, equipment and infrastructure expenses and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangibles, and utilities. We expect cost of revenue to generally increase in line with the increase in billable volume, however, we expect a future increase in amortization of acquired intangible assets that is not dependent on billed volume. We anticipate our cost per unit for existing tests will generally decrease over time due to the efficiencies we expect to gain as volume increases and from automation and other cost reductions. These reductions in cost per unit will likely be offset by new offerings which often have a higher costs per unit during the introductory phases before we are able to gain efficiencies. The cost per unit may fluctuate significantly from quarter to quarter.

Operating expenses

Our operating expenses are classified into three categories: research and development, selling and marketing, and general and administrative. For each category, the largest component is generally personnel-related costs, which include salaries, employee benefit costs, bonuses, commissions, as applicable, and stock-based compensation expense.

Research and development

Research and development expenses represent costs incurred to develop our technology and future offerings. These costs are principally for process development associated with our efforts to expand the number of genes we can evaluate, our efforts to lower the costs per unit and our development of new products to expand our platform. We have and may continue to partner with other companies to develop new technologies and capabilities we expect to invest capital and incur significant operating costs to support these development efforts. In addition, we incur process development costs to further develop the software we use to operate our laboratories, analyze generated data, process customer orders, validate clinical activities, enable ease of customer ordering, deliver reports and automate our business processes. These costs consist of personnel-related costs, laboratory supplies and equipment expenses, consulting costs, amortization of acquired intangible assets, and allocated overhead including rent, information technology, equipment depreciation and utilities.

We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to significantly increase as we continue our efforts to develop additional offerings, make investments to reduce costs, streamline our technology to provide patients access to testing, scale our business domestically and internationally and acquire and integrate new technologies. As a percentage of revenue, we expect research and development expenses to trend lower as we continue our efforts on scaling our business and operations and expanding our testing capabilities.

During October 2020 through our acquisition of ArcherDX, we recognized \$512.4 million of in-process R&D technology for two assets representing a therapy selection IVD and PCM technologies, both using an income approach. We estimate these technologies to be developed in the next few years with significant development costs through completion.

Selling and marketing

Selling and marketing expenses consist of personnel-related costs, including commissions, client service expenses, advertising and marketing expenses, educational and promotional expenses, market research and analysis, and allocated overhead including rent, information technology, equipment depreciation, amortization of

acquired intangibles, and utilities. We expect our selling and marketing expenses to increase as we continue to build our brand and focus on advertising our products and services. As a percentage of revenue, we expect our selling and marketing expenses to trend lower as we continue our efforts on scaling our business and operations and expanding our testing capabilities.

General and administrative

General and administrative expenses include executive, finance and accounting, billing and collections, legal and human resources functions as well as other administrative costs. These expenses include personnel-related costs; audit, accounting and legal expenses; consulting costs; allocated overhead including rent, information technology, equipment depreciation, and utilities; costs incurred in relation to our co-development agreements; and post-combination expenses incurred in relation to companies we acquire. We expect our general and administrative expenses to generally increase as we support continued growth of operations.

Change in fair value of contingent consideration

Changes in fair value of contingent consideration are adjustments to contingent consideration related to business combinations. We expect these changes to fluctuate significantly from period to period due to fair value adjustments that are dependent on many factors, including the value of our common stock and our assessment of the probability of meeting certain acquisition-related milestones within the terms of the respective acquisition agreements, including certain prescribed deadlines for achievement.

With respect to the ArcherDX final milestone, the liability was reduced to nil as of as of June 30, 2021 from \$262.5 million as of March 31, 2021 from \$287.7 million as of December 31, 2020, with the offsetting change recorded as changes in fair value of contingent consideration in our consolidated statements of operations. The removal of the liability balance and the associated change in fair value of contingent consideration was a result of our reassessment of the steps necessary to achieve clearance or approval based on FDA feedback received principally in the three months ended June 30, 2021. As a result of our reassessment, we do not believe achievement of the conditions will occur within the specified timeframe prescribed in the acquisition agreement. We expect FDA clearance or approval of a therapy selection IVD at a later date subject to resolution of the necessary steps.

Other income (expense), net

Other income (expense), net, primarily consists of adjustments to the fair value of our stock payable liabilities arising from business combinations, and we expect it to fluctuate significantly from period to period due to the volatility of our common stock. Other income (expense), net also includes income generated from our cash equivalents and marketable securities and amounts received under the CARES Act.

Interest expense

Interest expense is primarily attributable to interest incurred related to our debt financings and finance leases. See Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report for more details.

Income tax benefit

Since we generally establish a full valuation allowance against our deferred tax balances, our income tax benefit primarily consists of tax impacts of our deferred income tax assessments resulting from our acquisitions.

Critical accounting policies and estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. We evaluate our estimates on an ongoing basis. Our estimates are based on current facts, our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are

critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue recognition

We recognize revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers. We utilize the following practical expedients and exemptions:

- Costs to obtain or fulfill a contract are expensed when incurred because the amortization period would have been one year or less, and
- No adjustments to promised consideration were made for financing as we expect, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

Test revenue

Test revenue is comprised of testing services and sales of distributed precision oncology products.

The majority of our test revenue is generated from genetic testing, in addition to somatic testing for therapy selection and personalized cancer monitoring. These testing services provide analysis and associated interpretation of the sequencing of parts of the genome. Test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with biopharmaceutical partners, other business-to-business customers and insurance companies that include pricing provisions under which such tests are billed. Billing terms are generally net 30 to 60 days.

While the transaction price of diagnostic tests is originally established either via contract or pursuant to our standard list price, we often provide concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which we will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur. Making these estimates requires significant judgments based upon such factors as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. These judgments are reviewed each reporting period and updated as necessary.

We look to transfer of control in assessing timing of recognition of revenue in connection with each performance obligation. In general, revenue in connection with the service portion of our diagnostic tests is recognized upon delivery of the underlying clinical report or when the report is made available on our web portal. Outstanding performance obligations pertaining to orders received but for which the underlying report has not been issued are generally satisfied within a 30-day period.

We also generate test revenue through the sale of our precision oncology products, which is comprised primarily of sales of our distributed RUO and IVD products for therapy selection. We recognize revenue on these sales once shipment has occurred. Product sales are recorded net of discounts and other deductions. Billing terms are generally net 30 days.

Shipping and handling fees billed to customers are recorded as revenue on the consolidated statements of operations. The associated shipping and handling costs are recorded in cost of revenue.

Other revenue

Other revenue is primarily generated from pharma development services provided to biopharmaceutical companies related to companion diagnostic development as well as through collaboration agreements and genome network contracts.

Contracts for companion diagnostic development consist primarily of milestone-based payments along with annual fees and marked-up pass-through costs. The arrangements are treated as short-term contracts for revenue recognition purposes because they allow termination of the agreements by the customers with 30 to 120 days' written notice without a termination penalty. Upon termination, customers are required to pay for the proportion of services provided under milestones that were in progress. We recognize revenue in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenue over time based on the progress made toward achieving the performance obligation, utilizing input methods, including labor hours expended, tests processed, or time elapsed, that measure our progress toward the achievement of the milestone.

We also enter into collaboration and genome network contracts. Collaboration agreements provide customers with diagnostic testing and related data aggregation reporting services that are provided over the contract term. Collaboration revenue is recognized as the data and reporting services are delivered to the customer. Genome network offerings consist of subscription services related to a proprietary software platform designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis and treatment of hereditary disease. Such services are recognized on a straight-line basis over the subscription periods. Amounts due under collaboration and genome network agreements are typically billable on net 30-day terms.

Business combinations

We apply Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") 805, *Business Combinations*, which requires recognition of assets acquired, liabilities assumed, and contingent consideration at their fair value on the acquisition date with subsequent changes recognized in earnings; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination and expensed as incurred; requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset until completion or abandonment; and requires that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of provision for taxes.

We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. We base the estimated fair value of identifiable intangible assets acquired in a business combination on third-party valuations that use information and assumptions provided by our management, which consider our estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, estimated cost savings, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under ASC 480, *Distinguishing Liabilities from Equity*, we recognize a liability equal to the fair value of the contingent payments we expect to make as of the acquisition date. We remeasure this liability each reporting period and record changes in the fair value in change in fair value of contingent consideration in our consolidated statements of operations.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in our operating results from the date of acquisition.

Asset acquisitions

In circumstances where substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the asset is not considered a business and we account for the transaction as an asset acquisition. We recognize the assets acquired based on their relative fair value, which generally includes the transaction costs of the asset acquisition, and no gain or loss is recognized unless the fair value of noncash assets given as consideration differs from the assets' carrying amounts. The form of consideration transferred may be cash, liabilities incurred, or equity interests issued.

Goodwill and indefinite lived intangibles

In accordance with ASC 350, *Intangibles - Goodwill and Other* we do not amortize goodwill or other intangible assets with indefinite lives, including in-process research and development, but rather test them for impairment. ASC 350 requires us to perform an impairment review of our goodwill balance at least annually, which we do in the fourth quarter of each year for our single consolidated reporting unit, and whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. We did not incur any goodwill impairment losses in any of the periods presented.

Stock-based compensation

We incur stock-based compensation expense for awards granted to employees and directors and for inducement awards granted in connection with our business acquisitions. Stock-based compensation expense is measured at the date of grant and is based on the estimated fair value of the award. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and restricted stock unit ("RSU") awards, and on an accelerated basis for performance-based restricted stock unit ("PRSU") awards. We recognize stock-based compensation expense associated with PRSU grants when we determine the achievement of performance conditions is probable. In determining the fair value of stock options and employee stock purchase plan ("ESPP") purchases, we estimate the grant date fair value and the resulting stock-based compensation expense using the Black-Scholes option-pricing model. We estimate the grant date fair value of RSU and PRSU awards based on the grant date share price.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of stock-based awards. These assumptions include:

Expected term—The expected term represents the period that stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is based on the mid-point between the vesting date and the end of the contractual term.

Expected volatility—We estimate expected volatility based on the historical volatility of our common stock over a period equal to the expected term of awards and over the expected six-month term ESPP purchase periods.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of an option.

Dividend yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods.

Income taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Significant judgment is required in determining the net valuation allowance which includes our evaluation of all available evidence including past operating results, estimates on future taxable income and acquisition-related tax assets and liabilities. As of December 31, 2021, we recorded a full valuation allowance on our net deferred tax assets because we expect that it is more likely than not that our deferred tax assets will not be realized in the foreseeable future. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted.

Results of operations

A discussion regarding our financial condition and results of operations for the year ended December 31, 2021 compared to the year ended December 31, 2020 is presented below. A discussion regarding our financial condition and results of operations for the year ended December 31, 2020 compared to the year ended December 31, 2019 can be found under Part II, Item 7. in our Annual Report on Form 10-K for the year ended December 31, 2020.

Comparison of the Years Ended December 31, 2021 and 2020

	Year Ended December 31,		Dollar Change	% Change
	2021	2020		
Revenue:				
Test revenue	\$ 444,072	\$ 272,310	\$ 171,762	63%
Other revenue	16,377	7,288	9,089	125%
Total revenue	460,449	279,598	180,851	65%
Cost of revenue	348,669	198,275	150,394	76%
Research and development	416,087	240,605	175,482	73%
Selling and marketing	225,910	168,317	57,593	34%
General and administrative	248,070	270,029	(21,959)	(8)%
Change in fair value of contingent consideration	(386,646)	54,544	(441,190)	NM
Loss from operations	(391,641)	(652,172)	260,531	40%
Other income (expense), net	25,678	(32,332)	58,010	NM
Interest expense	(49,900)	(29,766)	(20,134)	(68)%
Net loss before taxes	(415,863)	(714,270)	298,407	42%
Income tax benefit	(36,857)	(112,100)	75,243	67%
Net loss	\$ (379,006)	\$ (602,170)	\$ 223,164	37%

NM - Not Meaningful

Revenue

The increase in revenue of \$180.9 million for the year ended December 31, 2021 compared to the same period in 2020 was due primarily to increased billable volume due to growth in our business. Billable volume increased to approximately 1,169,000 during the year ended December 31, 2021 compared to 659,000 in the same period in 2020, an increase of 77% due to growth in the business as well as lower billable volume in the prior year period as a result of the impact of COVID-19. Average revenue per unit decreased to \$380 during the year ended December 31, 2021 compared to \$413 in the same period in 2020, primarily due to changes in payer and product mix, as well as reductions in pricing for some payers as we focus on providing cost effective genetic testing.

Cost of revenue

The increase in the cost of revenue of \$150.4 million for the year ended December 31, 2021 compared to the same period in 2020 was primarily due to increased billable volume. For the year ended December 31, 2021, the number of units billed increased to approximately 1,169,000 from approximately 659,000 for the same period in 2020. Cost per unit was \$298 in 2021 compared to \$299 in 2020. The slight decrease in cost per unit is primarily attributable to the significant increase in billable volume in 2021. The billable volume during the prior year period was lower as a result of the impact of COVID-19. The decrease was offset by changes in product mix, an increase in amortization of acquired intangible assets of \$28.0 million, an increase in stock-based compensation of \$10.1 million as well as an increase in write downs of certain inventory items of \$9.7 million.

Research and development

The increase in research and development expense of \$175.5 million for the year ended December 31, 2021 compared to the same period in 2020 was due to the growth of the business as well as the impact of acquisitions. The increase in research and development expenses principally consisted of the following elements: personnel-related costs increased by \$83.3 million as a result of headcount growth; professional fees increased by \$32.4 million; lab-related expenses increased by \$20.8 million primarily due to costs related to lab services and supplies; technology costs increased by \$18.5 million due to higher spending on networking cloud computing services and software licenses; facilities-related expenses increased by \$8.3 million primarily due to expansion initiatives; acquisition and other expenses increased by \$6.3 million; and depreciation and amortization increased by \$5.9 million.

Selling and marketing

The increase in selling and marketing expenses of \$57.6 million for the year ended December 31, 2021 compared to the same period in 2020 was primarily due to the growth of the business and our increased spending on sales initiatives subsequent to our cut backs in the second quarter of 2020 in response to COVID-19. The increase in

selling and marketing expenses principally consisted of the following elements: personnel-related costs increased by \$39.0 million due to increases in headcount and sales commissions; marketing costs increased by \$6.3 million principally for branding initiatives and advertising; depreciation and amortization increased by \$2.9 million; information technology costs increased by \$2.9 million; facilities-related expenses by \$2.3 million; professional services and other increased by \$2.2 million; and travel and entertainment increased by \$2.0 million.

General and administrative

The decrease in general and administrative expenses of \$22.0 million for the year ended December 31, 2021 compared to the same period in 2020 was due to the nonrecurring effect of acquisitions in 2020, partially offset by growth in the business. Acquisition-related expenses declined by \$105.5 million due to the post-combination expense related to the acceleration of unvested equity from our acquisition of ArcherDX included in the prior year period. These decreases were partially offset by increases due to growth in the business including personnel-related costs, which increased by \$49.0 million primarily due to higher headcount; legal fees increased by \$14.3 million primarily for litigation-related expenses; professional services increased by \$11.8 million related to consulting services; and other corporate expenses increased by \$8.4 million.

Change in fair value of contingent consideration

The decrease in the change in fair value of contingent consideration of \$441.2 million for the year ended December 31, 2021 compared to the same period in 2020 was due principally to adjustments to decrease our contingent consideration liability related to ArcherDX resulting from a decrease in the value of our common stock and the removal of our contingent consideration liability relating to the outstanding milestone for FDA clearance or approval of a therapy selection IVD. The adjustments to decrease our contingent consideration were due to our determination that this milestone will not be achieved in the timeframe prescribed in the acquisition agreement, although we expect to receive FDA clearance or approval at a later date.

Other income (expense), net

The increase in other income (expense), net of \$58.0 million for the year ended December 31, 2021 compared to the same period in 2020 was principally due to fair value adjustments related to our stock payable liabilities resulting from business combinations of \$62.7 million due to the decrease in the price of our common stock, partially offset by amounts received under the CARES Act and the net changes in income recognized related to our marketable securities.

Interest expense

The increase in interest expense of \$20.1 million for the year ended December 31, 2021 compared to the same period in 2020 was principally due to increased debt outstanding as compared to the prior year period, partially offset by the impact of the adoption of Accounting Standards Update ("ASU") 2020-06, which reduced the interest expense recognized related to our convertible senior notes during 2021. See Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report.

Income tax benefit

The decrease in income tax benefit of \$75.2 million for the year ended December 31, 2021 compared to the same period in 2020 was primarily due to the net deferred tax liabilities assumed in connection with our acquisitions of One Codex, Genosity, Ciitizen and Stratify in 2021 which provided a future source of income to support the realization of our deferred tax assets and resulted in a partial release of our valuation allowance as compared to the partial release of our valuation allowance from our acquisition of YouScript and ArcherDX in 2020. As the short period tax returns for our 2021 acquisitions have not yet been filed, material changes to the tax returns may have a material impact on the net deferred tax liabilities assumed in connection with the acquisition and related income tax benefit.

Liquidity and capital resources

Liquidity and capital expenditures

We have generally incurred net losses since our inception. For the years ended December 31, 2021, 2020 and 2019, our net losses were \$379.0 million, \$602.2 million and \$242.0 million, respectively, and we expect to incur additional losses in the future. At December 31, 2021, we had an accumulated deficit of \$1.7 billion. While our revenue has increased over time, we may never achieve revenue sufficient to offset our expenses.

Since inception, our operations have been financed primarily by fees collected from our customers, net proceeds from sales of our capital stock as well as borrowing from debt facilities and the issuance of convertible senior notes.

In April 2020, we issued, in an underwritten public offering, an aggregate of 20.4 million shares of our common stock at a price of \$9.00 per share, for gross proceeds of \$184.0 million and net proceeds of \$173.0 million. In 2020, we issued 3.6 million shares of common stock at an average price of \$26.33 per share in an "at the market" offering for aggregate proceeds of \$93.7 million and net proceeds of \$90.7 million. In January 2021, we issued, in an underwritten public offering, an aggregate of 8.9 million shares of our common stock at a price of \$51.50 per share, for gross proceeds of \$460.0 million and net proceeds of approximately \$434.3 million.

In September 2019, we issued \$350.0 million of aggregate principal amount of convertible senior notes due 2024, which bear cash interest at a rate of 2.0% per year. Also in September 2019, we used the funds received through the issuance of our convertible senior notes due 2024 to settle our 2018 Note Purchase Agreement we entered into in November 2018. In April 2021, we issued \$1,150.0 million aggregate principal amount of convertible senior notes due 2028, which bear cash interest at a rate of 1.5% per year.

In October 2020 in connection with our acquisition of ArcherDX, we issued \$275.0 million of our common stock in a private placement at a price of \$16.85 per share. We also entered into a credit facility to borrow \$135.0 million. The private placement and credit facility closed concurrently with the merger in October 2020. The terms of this credit facility restrict our ability to incur certain indebtedness, pay dividends, make acquisitions and take other actions.

At December 31, 2021 and 2020, we had \$1.1 billion and \$360.7 million, respectively, of cash, cash equivalents, restricted cash and marketable securities.

Our primary uses of cash are to fund our operations as we continue to grow our business, enter into partnerships and acquire businesses and technologies. Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We estimate our capital expenditures will be approximately \$60.0 million for 2022.

We have incurred substantial losses since inception, and we expect to continue to incur losses in the future. We believe our existing cash, cash equivalents and marketable securities as of December 31, 2021 and fees collected from the sale of our products and services will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

We may need or choose to raise additional funding to finance operations prior to achieving profitability or should we make additional acquisitions. We regularly consider fundraising opportunities and will determine the timing, nature and size of future financings based upon various factors, including market conditions and our operating plans. We may in the future elect to finance operations by selling equity or debt securities or borrowing money. We also may elect to finance future acquisitions. If we issue equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing additional debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. In addition, the terms of additional debt securities or borrowings could impose significant restrictions on our operations. If additional funding is required, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all. If we are unable to obtain additional funding when needed, we may need to curtail planned activities to reduce costs. Doing so will likely have an unfavorable effect on our ability to execute on our business plan and have an adverse effect on our business, results of operations and future prospects.

The following table summarizes our cash flows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Cash used in operating activities	\$ (559,815)	\$ (298,502)	\$ (145,053)
Cash used in investing activities	(204,080)	(400,583)	(280,310)
Cash provided by financing activities	1,565,940	672,993	464,771
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 802,045</u>	<u>\$ (26,092)</u>	<u>\$ 39,408</u>

Cash flows from operating activities

For the year ended December 31, 2021, cash used in operating activities was \$559.8 million and principally resulted from our net loss of \$379.0 million, non-cash charges for remeasurements of liabilities associated with business combinations of \$411.8 million primarily related to ArcherDX development milestones and a \$36.9 million income tax benefit primarily generated from our acquisitions of One Codex, Genosity, Ciitizen and Stratify. These were partially offset by non-cash charges of \$180.1 million for stock-based compensation, \$80.5 million for depreciation and amortization, \$14.2 million for amortization of debt discount and issuance costs related to our outstanding debt, \$9.5 million of post-combination expense primarily comprised of hold-back cash consideration related to our acquisition of Ciitizen and the acceleration of unvested equity from our acquisition of One Codex, \$6.2 million of amortization of premiums on investment securities and \$5.0 million of other adjustments. The net effect on cash for changes in net operating assets was a decrease of cash of \$27.6 million due principally to increases in accounts receivable due to timing of collections, inventory and accounts payable, partially offset by increases in accrued liabilities.

For the year ended December 31, 2020, cash used in operating activities was \$298.5 million and principally resulted from our net loss of \$602.2 million and \$112.1 million related to our income tax benefit generated from business combinations completed in 2020 partially offset by noncash charges of \$158.7 million for stock-based compensation, \$92.3 million in remeasurements of liabilities associated with business combinations such as contingent consideration, \$91.0 million related to post-combination expense due to the acceleration of unvested equity in the acquisition of ArcherDX, \$39.1 million for depreciation and amortization, \$17.2 million of amortization of debt discount and issuance costs and \$1.4 million of other adjustments. The net effect on cash for changes in net operating assets was an inflow of cash of \$16.0 million due principally to increases in accounts payable and accrued liabilities partially offset by increases in inventory and accounts receivable due to timing of collections.

For the year ended December 31, 2019, cash used in operating activities of \$145.1 million principally resulted from our net loss of \$242.0 million and \$18.5 million related to our income tax benefit generated from business combinations completed in 2019 offset by non-cash charges of \$75.9 million for stock-based compensation, \$16.2 million for depreciation and amortization, \$8.9 million for debt extinguishment costs related to the settlement of our 2018 Note Purchase Agreement and \$1.1 million of other adjustments. The net effect on cash for changes in net operating assets was a use of cash of \$8.8 million due principally to increases in accrued liabilities which include acquisition-related liabilities for 2019 business acquisitions partially offset by increases in accounts receivable due to timing of collections and increases in prepaid expenses and other current assets.

Cash flows from investing activities

For the year ended December 31, 2021, cash used in investing activities of \$204.1 million was primarily due to net cash used to acquire One Codex, Genosity and Ciitizen of \$247.4 million and cash used for purchases of property and equipment of \$54.7 million, partially offset by proceeds from net maturities and purchases of marketable securities of \$99.3 million.

For the year ended December 31, 2020, cash used in investing activities of \$400.6 million was primarily related to net cash used to acquire Orbicule BV ("Diploid"), Genelex, YouScript and ArcherDX of \$383.8 million, purchases of property and equipment of \$22.9 million, and other cash outflows of \$4.0 million, all partially offset by net sales and maturities of marketable securities of \$10.1 million.

For the year ended December 31, 2019, cash used in investing activities of \$280.3 million resulted primarily from purchases of marketable securities exceeding proceeds from maturities and sales of marketable securities by \$226.4 million, net cash used to acquire Singular Bio, Jungla Inc., and Clear Genetics, Inc. of \$33.8 million and purchases of property and equipment of \$20.0 million.

Cash flows from financing activities

For the year ended December 31, 2021, cash provided by financing activities of \$1.6 billion primarily consisted of net proceeds from the issuance of convertible senior notes due 2024 of \$1.1 billion and the public offering of common stock of \$434.3 million as well as cash received from issuances of common stock totaling \$23.8 million.

For the year ended December 31, 2020, cash provided by financing activities of \$673.0 million consisted of cash received from issuances of common stock totaling \$284.2 million, including cash received from shares issued through a private placement in October 2020 upon the close of the ArcherDX acquisition, exercises of stock options and employee stock plan purchases; net proceeds from the public offerings of common stock of \$263.7 million; and net proceeds from debt financings of \$129.2 million. These cash inflows were partially offset by other cash outflows of \$4.1 million.

For the year ended December 31, 2019, cash provided by financing activities of \$464.8 million consisted of net proceeds from the issuance of convertible senior notes due 2028 of \$339.9 million, net proceeds from the public offerings of common stock of \$204.0 million and cash received from issuances of common stock totaling \$9.5 million, including cash received from exercises of stock options of \$3.5 million and employee stock plan purchases of \$5.8 million. These cash inflows were partially offset by payments related to the settlement of our 2018 Note Purchase Agreement through repayment of loan obligations of \$75.0 million and payment of debt extinguishment costs of \$10.6 million, as well as finance lease payments of \$2.1 million.

Contractual obligations

The following table summarizes our contractual obligations, including interest, as of December 31, 2021 (in thousands):

Contractual obligations:	2022	2023 and 2024	2025 and 2026	2027 and beyond	Total
Operating leases	\$ 18,470	\$ 51,108	\$ 50,678	\$ 80,464	\$ 200,720
Finance leases	4,719	5,891	177	—	10,787
Convertible senior notes	—	349,996	—	1,150,000	1,499,996
2020 Term Loan	—	135,000	—	—	135,000
Purchase commitments	25,893	29,271	614	—	55,778
Total	\$ 49,082	\$ 571,266	\$ 51,469	\$ 1,230,464	\$ 1,902,281

See Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report for additional details regarding our leases, convertible senior notes, 2020 Term Loan and purchase commitments.

Off-balance sheet arrangements

We have not entered into any off-balance sheet arrangements.

Recent accounting pronouncements

See "Recent accounting pronouncements" in Note 2, "Summary of significant accounting policies" in Notes to Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and accounting pronouncements not yet adopted, and their expected effect on our financial position and results of operations.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. Our cash, cash equivalents, restricted cash and marketable securities totaled \$1.1 billion at December 31, 2021, and consisted primarily of bank deposits, money market funds, U.S. Treasury notes and U.S. government agency securities. Such interest-bearing instruments carry a degree of risk; however, because our investments are primarily high-quality credit instruments with short-term durations with high-quality institutions, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. At December 31, 2021, a hypothetical 1.0% (100 basis points) increase or decrease in interest rates would not have resulted in a material change in the fair value of our cash equivalents and marketable securities. Fluctuations in the value of our cash equivalents and marketable securities caused by a change in interest rates (gains or losses on the carrying value) are recorded in other comprehensive gain (loss) and are realized if we sell the underlying securities prior to maturity.

Our 2020 Term Loan bears interest at an annual rate equal to three-month LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75% and is therefore sensitive to changes in interest rates. If three-month LIBOR can no longer be determined or if the applicable governmental authority ceases to supervise or sanction such rates, then we will endeavor to agree with the administrative agent, an alternate rate of interest that gives due consideration to the then prevailing market convention for determining interest for comparable loans in the United States; provided that until such alternative rate of interest is agreed, the 2020 Term Loan shall bear interest at the *Wall Street Journal* Prime Rate. We currently do not use interest rate derivative instruments to manage our exposure to interest rate fluctuations.

Although our convertible senior notes are based on a fixed rate, changes in interest rates could impact their fair market value. As of December 31, 2021, the fair market value of the convertible senior notes due 2024 and due 2028 was \$325.6 million and \$1.2 billion, respectively. For additional information about the convertible senior notes, see Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report.

ITEM 8. Consolidated Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Invitae Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Invitae Corporation (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 1, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating

Measurement of test revenue billed to insurance carriers

Description of the Matter

During the year ended December 31, 2021, the Company recognized test revenue billed to insurance carriers of \$276.9 million. As discussed in Note 2 to the consolidated financial statements, the Company often provides concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which the Company will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur.

Auditing the measurement of the Company's test revenue billed to insurance carriers was complex and judgmental due to the significant estimation required in determining the amount expected to be collected. In particular, the estimate of test revenue billed to insurance carriers was affected by assumptions in payer behavior such as changes in historical payment patterns, contract provisions and government and private insurance reimbursement policies.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's revenue recognition process. As part of our testing, we considered controls over management's review of the significant assumptions and inputs used in the determination of the amount expected to be collected. We also tested controls used by management to compare the current and historical data used in making the estimates for completeness and accuracy.

Our audit procedures over the Company's test revenue billed to insurance carriers included, among others, assessing valuation methodologies and models and testing the significant assumptions and the underlying data used by the Company in its analysis. We agreed a sample of transactions to the payer contract terms. We compared the significant assumptions and inputs used by management to changes in the Company's contracted rates, government and private insurance payer collection trends, and other relevant factors. We assessed the historical accuracy of the cash collections used in the Company's revenue models and assessed the completeness of adjustments to estimates of future cash collections as a result of significant contract amendments and changes in collection trends.

Valuation of intangible assets and resulting goodwill associated with business combinations

Description of the Matter

As described in Note 4 to the consolidated financial statements, the Company completed several business combinations during 2021. As a result of the business combinations, the Company recorded intangibles assets of \$193.7 million and goodwill of \$420.6 million. .

Auditing the Company's accounting for the business combinations was challenging as the determination of the fair value of the intangible assets and resulting goodwill acquired was based on subjective estimates and assumptions. The Company used an income approach to measure the acquired intangible assets. The valuation of the intangible assets and resulting goodwill was subject to higher estimation uncertainty due to management's judgments in determining significant assumptions that included assumed revenue growth and discount rates. Changes in these significant assumptions could have a significant effect on the fair value of the intangible assets and resulting goodwill.

How We Addressed the Matter in Our Audit

We tested the design and operating effectiveness of internal controls over the Company's process for accounting for business combinations. For example, we tested controls over management's review of the valuation of intangible assets including the review of the valuation model and significant assumptions used.

Our audit procedures related to the valuation of intangible assets and resulting goodwill included, among others, utilizing a valuation specialist to assist in evaluating the appropriateness of the Company's valuation models and evaluating the reasonableness of significant assumptions used such as the revenue growth and the discount rates as compared to industry and market data and historical results. We also evaluated whether the significant assumptions used were reasonable by comparing them to the past performance of prior business combinations, current industry data and current market forecasts, and whether such assumptions were consistent with evidence obtained in other areas of the audit.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.

Redwood City, California

March 1, 2022

INVITAE CORPORATION

Consolidated Balance Sheets

(in thousands, except par value data)

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 923,250	\$ 124,794
Marketable securities	122,121	229,186
Accounts receivable	66,227	47,722
Inventory	33,516	32,030
Prepaid expenses and other current assets	33,691	20,200
Total current assets	<u>1,178,805</u>	<u>453,932</u>
Property and equipment, net	114,714	66,102
Operating lease assets	121,169	45,109
Restricted cash	10,275	6,686
Intangible assets, net	1,187,994	981,845
Goodwill	2,283,059	1,863,623
Other assets	23,551	13,188
Total assets	<u>\$ 4,919,567</u>	<u>\$ 3,430,485</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 21,127	\$ 25,203
Accrued liabilities	106,453	86,058
Operating lease obligation	12,359	8,789
Finance lease obligation	4,156	1,695
Total current liabilities	<u>144,095</u>	<u>121,745</u>
Operating lease obligation, net of current portion	124,369	48,357
Finance lease obligation, net of current portion	5,683	3,123
Debt	113,391	104,449
Convertible senior notes, net	1,464,138	283,724
Deferred tax liability	51,696	51,538
Other long-term liabilities	37,797	841,256
Total liabilities	<u>1,941,169</u>	<u>1,454,192</u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value: 20,000 shares authorized; nil and 125 shares issued and outstanding as of December 31, 2021 and 2020, respectively	—	—
Common stock, \$0.0001 par value: 400,000 shares authorized; 228,116 and 185,886 shares issued and outstanding as of December 31, 2021 and 2020, respectively	23	19
Accumulated other comprehensive (loss) income	(7)	1
Additional paid-in capital	4,701,230	3,337,120
Accumulated deficit	(1,722,848)	(1,360,847)
Total stockholders' equity	<u>2,978,398</u>	<u>1,976,293</u>
Total liabilities and stockholders' equity	<u>\$ 4,919,567</u>	<u>\$ 3,430,485</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Operations

(in thousands, except per share data)

	Year Ended December 31,		
	2021	2020	2019
Revenue:			
Test revenue	\$ 444,072	\$ 272,310	\$ 212,473
Other revenue	16,377	7,288	4,351
Total revenue	<u>460,449</u>	<u>279,598</u>	<u>216,824</u>
Cost of revenue	348,669	198,275	118,103
Research and development	416,087	240,605	141,526
Selling and marketing	225,910	168,317	122,237
General and administrative	248,070	270,029	78,963
Change in fair value of contingent consideration	(386,646)	54,544	107
Total costs and operating expenses	<u>852,090</u>	<u>931,770</u>	<u>460,936</u>
Loss from operations	(391,641)	(652,172)	(244,112)
Other income (expense), net	25,678	(32,332)	(3,891)
Interest expense	(49,900)	(29,766)	(12,412)
Net loss before taxes	<u>(415,863)</u>	<u>(714,270)</u>	<u>(260,415)</u>
Income tax benefit	(36,857)	(112,100)	(18,450)
Net loss	<u>\$ (379,006)</u>	<u>\$ (602,170)</u>	<u>\$ (241,965)</u>
Net loss per share, basic and diluted	<u>\$ (1.80)</u>	<u>\$ (4.47)</u>	<u>\$ (2.66)</u>
Shares used in computing net loss per share, basic and diluted	<u>210,946</u>	<u>134,587</u>	<u>90,859</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Comprehensive Loss

(in thousands)

	Year Ended December 31,		
	2021	2020	2019
Net loss	\$ (379,006)	\$ (602,170)	\$ (241,965)
Other comprehensive (loss) income:			
Unrealized (loss) income on available-for-sale marketable securities, net of tax	(8)	10	(4)
Comprehensive loss	<u>\$ (379,014)</u>	<u>\$ (602,160)</u>	<u>\$ (241,969)</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Stockholders' Equity

(in thousands)

	Year Ended December 31,		
	2021	2020	2019
Common stock:			
Balance, beginning of period	\$ 19	\$ 10	\$ 8
Common stock issued	4	9	2
Balance, end of period	<u>23</u>	<u>19</u>	<u>10</u>
Accumulated other comprehensive (loss) income:			
Balance, beginning of period	1	(9)	(5)
Unrealized (loss) income on available-for-sale marketable securities, net of tax	(8)	10	(4)
Balance, end of period	<u>(7)</u>	<u>1</u>	<u>(9)</u>
Additional paid-in capital:			
Balance, beginning of period	3,337,120	1,138,316	678,548
Common stock issued in private placement, net	—	263,628	—
Common stock issued in connection with public offering, net	434,263	263,685	204,024
Common stock issued on exercise of stock options, net	8,984	10,730	3,456
Common stock issued pursuant to exercises of warrants	1,242	974	181
Common stock issued pursuant to employee stock purchase plan	13,550	8,871	5,833
Common stock issued or issuable pursuant to acquisitions and equity awards issued in connection with such acquisitions	805,124	1,524,227	133,942
Equity component of convertible senior notes, net	—	—	75,488
Warrants issued pursuant to loan agreement	—	27,000	—
Stock-based compensation expense	176,435	110,076	36,844
Reclassification of equity component of convertible senior notes	(75,488)	—	—
Reclassification of stock payable liabilities	—	(10,387)	—
Balance, end of period	<u>4,701,230</u>	<u>3,337,120</u>	<u>1,138,316</u>
Accumulated deficit:			
Balance, beginning of period	(1,360,847)	(758,677)	(516,712)
Cumulative effect of accounting change	17,005	—	—
Net loss	(379,006)	(602,170)	(241,965)
Balance, end of period	<u>(1,722,848)</u>	<u>(1,360,847)</u>	<u>(758,677)</u>
Total stockholders' equity	<u>\$ 2,978,398</u>	<u>\$ 1,976,293</u>	<u>\$ 379,640</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2021	2020	2019
Cash flows from operating activities:			
Net loss	\$ (379,006)	\$ (602,170)	\$ (241,965)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	80,472	39,050	16,206
Stock-based compensation	180,075	158,747	75,948
Amortization of debt discount and issuance costs	14,226	17,204	4,416
Remeasurements of liabilities associated with business combinations	(411,842)	92,348	—
Benefit from income taxes	(36,857)	(112,100)	(18,450)
Debt extinguishment costs	—	—	8,926
Post-combination expense for acceleration of unvested equity and deferred stock compensation	9,530	91,021	—
Amortization of premiums and discounts on investment securities	6,221	1,236	(296)
Other	4,983	189	1,391
Changes in operating assets and liabilities, net of businesses acquired:			
Accounts receivable	(16,696)	(2,814)	(6,131)
Inventory	(1,486)	(7,832)	1,645
Prepaid expenses and other current assets	(14,563)	(2,010)	(6,624)
Other assets	(3,274)	895	2,026
Accounts payable	(9,258)	10,186	1,558
Accrued expenses and other long-term liabilities	17,660	17,548	16,297
Net cash used in operating activities	<u>(559,815)</u>	<u>(298,502)</u>	<u>(145,053)</u>
Cash flows from investing activities:			
Purchases of marketable securities	(325,957)	(280,258)	(260,917)
Proceeds from sales of marketable securities	—	12,832	—
Proceeds from maturities of marketable securities	425,293	277,487	34,500
Acquisition of businesses, net of cash acquired	(247,396)	(383,753)	(33,846)
Purchases of property and equipment	(54,720)	(22,865)	(20,047)
Other	(1,300)	(4,026)	—
Net cash used in investing activities	<u>(204,080)</u>	<u>(400,583)</u>	<u>(280,310)</u>
Cash flows from financing activities:			
Proceeds from public offerings of common stock, net	434,263	263,688	204,024
Proceeds from issuance of common stock	23,767	284,203	9,470
Proceeds from issuance of convertible senior notes, net	1,116,427	—	339,900
Proceeds from issuance of debt, net	—	129,214	—
Payments of debt extinguishment costs	—	—	(10,638)
Loan payments	—	—	(75,000)
Finance lease principal payments	(3,759)	(2,655)	(2,075)
Other	(4,758)	(1,457)	(910)
Net cash provided by financing activities	<u>1,565,940</u>	<u>672,993</u>	<u>464,771</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>802,045</u>	<u>(26,092)</u>	<u>39,408</u>
Cash, cash equivalents and restricted cash at beginning of period	<u>131,480</u>	<u>157,572</u>	<u>118,164</u>
Cash, cash equivalents and restricted cash at end of period	<u>\$ 933,525</u>	<u>\$ 131,480</u>	<u>\$ 157,572</u>
Supplemental cash flow information:			
Interest paid	\$ 31,400	\$ 12,130	\$ 4,731
Supplemental cash flow information of non-cash investing and financing activities:			
Equipment acquired through finance leases	\$ 8,224	\$ 4,463	\$ 1,892
Purchases of property and equipment in accounts payable and accrued liabilities	\$ 13,222	\$ 1,869	\$ 2,422
Warrants issued pursuant to debt agreement	\$ —	\$ 27,000	\$ —
Common stock issued for acquisition of businesses	\$ 802,073	\$ 1,157,958	\$ 108,573
Consideration payable for acquisition of businesses	\$ 46,649	\$ 940,829	\$ 21,449
Operating lease assets obtained in exchange for lease obligations, net	\$ 88,777	\$ 14,058	\$ 4,261

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Notes to Consolidated Financial Statements

1. Organization and description of business

Invitae Corporation ("Invitae," "the Company," "we," "us," and "our") was incorporated in the State of Delaware on January 13, 2010, as Locus Development, Inc. and we changed our name to Invitae Corporation in 2012. We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, personalized oncology, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets and businesses that further expand our test menu and suite of genome management offerings and accelerated our entry into key genomics markets. We are building a platform to harness genetics on a global scale to diagnose more patients correctly, earlier and bring therapies to market faster. Our genome management offerings will provide information services to the patient that are intended to enhance the customer experience through personalized insights, technology-enabled services and network connections that inform genetic healthcare throughout life. Invitae operates in one segment.

2. Summary of significant accounting policies

Principles of consolidation

Our consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. We base these estimates on current facts, historical and anticipated results, trends and various other assumptions that we believe are reasonable under the circumstances, including assumptions as to future events. Actual results could differ materially from those judgments, estimates and assumptions. We evaluate our estimates on an ongoing basis.

Significant estimates and assumptions made by management include the determination of:

- revenue recognition;
- inventory adjustments;
- the fair value of assets and liabilities associated with business combinations;
- the valuation of our 2.00% convertible senior notes due 2024 issued in September 2019 and our 1.5% convertible senior notes due 2028 issued in April 2021 (collectively, our "Convertible Senior Notes");
- our incremental borrowing rates used to calculate our lease balances;
- stock-based compensation expense and the fair value of awards and warrants issued; and
- income tax uncertainties.

Prior period reclassifications

We have reclassified certain amounts in prior periods to conform with current presentation. During the current period, we have disclosed the change in fair value of our contingent consideration separately in our statements of operations. These amounts are general and administrative in nature and were disclosed in general and administrative expense in previous periods.

Immaterial correction of an error

We determined the historical classification of certain acquisition-related obligations as equity and the subsequent measurement of such obligations was inappropriate and instead should have been classified as liabilities and subsequently measured at fair value with changes recognized in other expense, net during the year ended December 31, 2020. We determined that the impact of the error to previously issued consolidated financial statements was not material and have corrected the immaterial error in the current period financial statements. The impact of this correction was an increase to other long-term liabilities of \$10.1 million, a corresponding decrease to additional paid-in capital of \$10.4 million and an increase to other income, net of \$0.3 million.

Concentrations of credit risk and other risks and uncertainties

Financial instruments that potentially subject us to a concentration of credit risk consist of cash, cash equivalents, marketable securities and accounts receivable. Our cash and cash equivalents are held by financial institutions in the United States. Such deposits may exceed federally insured limits.

Significant customers are those that represent 10% or more of our total revenue for each year presented on the consolidated statements of operations. Our revenue from significant customers as a percentage of our total revenue was as follows:

	Year Ended December 31,		
	2021	2020	2019
Medicare	15 %	19 %	25 %

No customers represented more than 10% of accounts receivable as of December 31, 2021 and 2020.

Cash, cash equivalents, and restricted cash

We consider all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds, U.S. Treasury notes and government agency securities.

Restricted cash consists primarily of money market funds that secure irrevocable standby letters of credit that serve as collateral for security deposits for our facility leases.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows (in thousands):

	December 31,	
	2021	2020
Cash and cash equivalents	\$ 923,250	\$ 124,794
Restricted cash	10,275	6,686
Total cash, cash equivalents and restricted cash	<u>\$ 933,525</u>	<u>\$ 131,480</u>

Restricted cash serves as the security deposit for the Company's leases.

Marketable securities

All marketable securities have been classified as "available-for-sale" and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its marketable debt securities at the time of purchase and reevaluates such designation at each balance sheet date. Short-term marketable securities have maturities one year or less at the balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive loss. Realized gains and losses and impairments, if any, on available-for-sale securities are included in other expense, net. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in other income (expense), net.

For marketable securities in an unrealized loss position, we assess our intent to sell, or whether it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. If either of these criteria are met, the security's amortized cost basis is written down to fair value through other income (expense), net.

Accounts receivable

We receive payment from patients, biopharmaceutical partners, third-party payers and other business-to-business customers. See Note 3, "Revenue, accounts receivable and deferred revenue" for further information.

Allowances for losses on certain financial assets

We assess our accounts receivables for expected credit losses at each reporting period by disaggregating by payer type and further by portfolios of customers with similar characteristics, such as customer type and geographic location. We then review each portfolio for expected credit losses based on historical payment trends as well as forward looking data and current economic trends. If a credit loss is determined, we record a reduction to our accounts receivable balance with a corresponding general and administrative expense.

We review available-for-sale debt securities in an unrealized loss positions quarterly and assess whether such unrealized loss positions are credit-related. Our expected loss allowance methodology for these securities is developed by reviewing the extent of the unrealized loss, the issuers' credit ratings and any changes in those ratings, as well as reviewing current and future economic market conditions and the issuers' current status and financial condition. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income (expense), net. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive income (loss).

Deferred revenue

We record a contract liability when cash payments are received or due in advance of our performance related to one or more performance obligations. See Note 3, "Revenue, accounts receivable and deferred revenue" for further information.

Inventory

Our inventory consists of raw materials, work in progress, and finished goods, which are stated at the lower of cost or net realizable value on a first-in, first-out basis. We periodically analyze our inventory levels and expiration dates, and write down inventory that has become obsolete, inventory that has a cost basis in excess of its net realizable value, and inventory in excess of expected sales requirements as cost of revenue. We record an allowance for obsolete inventory using an estimate based on historical trends and evaluation of near-term expirations.

Business combinations

We apply ASC 805, *Business Combinations*, which requires recognition of assets acquired, liabilities assumed, and contingent consideration at their fair value on the acquisition date with subsequent changes recognized in earnings; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination and expensed as incurred; requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset until completion or abandonment; and requires that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of provision for taxes.

We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. We base the estimated fair value of identifiable intangible assets acquired in a business combination on third-party valuations that use information and assumptions provided by our management, which consider our estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, estimated cost savings, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under ASC 480, *Distinguishing Liabilities from Equity*, we recognize a liability equal to the fair value of the contingent payments we expect to make as of the acquisition date. We remeasure this liability each reporting period and record changes in the fair value in change in fair value of contingent consideration in our consolidated statements of operations.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in our operating results from the date of acquisition.

Asset acquisitions

In circumstances where substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the asset is not considered a business and we account for the transaction as an asset acquisition. We recognize the assets acquired based on their relative fair value, which generally includes the transaction costs of the asset acquisition, and no gain or loss is recognized unless the fair value of noncash assets given as consideration differs from the assets' carrying amounts. The form of consideration transferred may be cash, liabilities incurred, or equity interests issued.

Intangible assets

Amortizable intangible assets include trade names, non-compete agreements, patent licensing agreements, favorable leases, developed technology, customer relationships, and rights to develop new technology acquired as part of business combinations. Customer relationships acquired through our business combinations in 2017 are amortized on an accelerated basis, utilizing free cash flows, over periods ranging from five to 11 years. All other intangible assets subject to amortization are amortized using the straight-line method over their estimated useful lives ranging from five to 15 years. All intangible assets subject to amortization are reviewed for impairment in accordance with ASC 360, *Property, Plant and Equipment*.

Goodwill

In accordance with ASC 350, *Intangibles-Goodwill and Other*, our goodwill is not amortized but is tested for impairment on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. Under ASC 350, we perform annual impairment reviews of our goodwill balance during the fourth fiscal quarter or more frequently if business factors indicate. In testing for impairment, we compare the fair value of our reporting unit to its carrying value including the goodwill of that unit. If the carrying value, including goodwill, exceeds the reporting unit's fair value, we will recognize an impairment loss for the amount by which the carrying amount exceeds the reporting unit's fair value. The loss recognized cannot exceed the total amount of goodwill allocated to that reporting unit. We did not incur any goodwill impairment losses in any of the periods presented.

In-process research and development

Intangible assets related to in-process research and development costs ("IPR&D") are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. During this period, the assets will not be amortized but will be tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts.

During the fourth quarter and if business factors indicate more frequently, we perform an assessment of the qualitative factors affecting the fair value of our IPR&D projects. If the fair value exceeds the carrying value, there is no impairment. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of an asset to its carrying value, without consideration of any recoverability test. We have not identified any such impairment losses to date.

Leases

Under ASC 842, *Leases*, we determine if an arrangement is a lease at inception. Operating leases are included in operating lease assets and operating lease obligations in our consolidated balance sheets. Finance leases are included in other assets and finance lease obligations in our consolidated balance sheets.

Lease assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at commencement based on the present value of lease payments over the lease term. We generally use our incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments. The operating lease asset also includes any lease payments made and is adjusted for lease incentives. Our lease terms may include options to extend or terminate the lease which are recognized when it is reasonably certain that we will exercise that option. Leases with terms of 12 months or less are not recorded on our balance sheet. Lease expense is recognized on a straight-line basis over the lease terms, or in some cases, the useful life of the underlying asset. We account for the lease and non-lease components as a single lease component.

Property and equipment, net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and seven years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

The estimated useful lives of property and equipment are as follows:

Furniture and fixtures	7 years
Automobiles	7 years
Manufacturing and Laboratory equipment	5 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	Shorter of lease term or estimated useful life

Long-lived assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows or other appropriate measures of fair value. There were no long-lived asset impairment losses recorded for any period presented.

Fair value of financial instruments

Our financial instruments consist principally of cash and cash equivalents, marketable securities, accounts payable, accrued liabilities, finance leases, and liabilities associated with business combinations. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued and other current liabilities approximate their current fair value due to the relatively short-term nature of these accounts. Based on borrowing rates available to us, the carrying value of finance leases approximate their fair values. Liabilities associated with business combinations are recorded at their estimated fair value.

Revenue recognition

We recognize revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers. We utilize the following practical expedients and exemptions:

- Costs to obtain or fulfill a contract are expensed when incurred because the amortization period would have been one year or less, and
- No adjustments to promised consideration were made for financing as we expect, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

Test revenue

Test revenue is comprised of testing services and sales of distributed precision oncology products.

The majority of our test revenue is generated from genetic testing, in addition to somatic testing for therapy selection and personalized cancer monitoring. These testing services provide analysis and associated interpretation of the sequencing of parts of the genome. Test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with biopharmaceutical partners, other business-to-business customers and insurance companies that include pricing provisions under which such tests are billed. Billing terms are generally net 30 to 60 days.

While the transaction price of diagnostic tests is originally established either via contract or pursuant to our standard list price, we often provide concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which we will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur. Making these estimates requires significant judgments based upon such factors as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. These judgments are reviewed each reporting period and updated as necessary.

We look to transfer of control in assessing timing of recognition of revenue in connection with each performance obligation. In general, revenue in connection with the service portion of our diagnostic tests is recognized upon delivery of the underlying clinical report or when the report is made available on our web portal. Outstanding performance obligations pertaining to orders received but for which the underlying report has not been issued are generally satisfied within a 30-day period.

We also generate test revenue through the sale of our precision oncology products, which is comprised primarily of sales of our distributed RUO and IVD products for therapy selection. We recognize revenue on these sales once shipment has occurred. Product sales are recorded net of discounts and other deductions. Billing terms are generally net 30 days.

Shipping and handling fees billed to customers are recorded as revenue on the consolidated statements of operations. The associated shipping and handling costs are recorded as cost of revenue.

Other revenue

Other revenue is primarily generated from pharma development services provided to biopharmaceutical companies related to companion diagnostic development as well as through collaboration agreements and genome network contracts.

Contracts for companion diagnostic development consist primarily of milestone-based payments along with annual fees and marked-up pass-through costs. The arrangements are treated as short-term contracts for revenue recognition purposes because they allow termination of the agreements by the customers with 30 to 120 days' written notice without a termination penalty. Upon termination, customers are required to pay for the proportion of services provided under milestones that were in progress. We recognize revenue in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenue over time based on the progress made toward achieving the performance obligation, utilizing input methods, including labor hours expended, tests processed, or time elapsed, that measure our progress toward the achievement of the milestone.

We also enter into collaboration and genome network contracts. Collaboration agreements provide customers with diagnostic testing and related data aggregation reporting services that are provided over the contract term. Collaboration revenue is recognized as the data and reporting services are delivered to the customer. Genome network offerings consist of subscription services related to a proprietary software platform designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis and treatment of hereditary disease. Such services are recognized on a straight-line basis over the subscription periods. Amounts due under collaboration and genome network agreements are typically billable on net 30-day terms.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering our products and services and includes expenses for materials and supplies, personnel-related costs, freight, costs for lab services and clinical trial support, equipment and infrastructure expenses and allocated overhead including rent, information technology costs, equipment depreciation, amortization of acquired intangibles, and utilities.

License Agreements

We have entered and may continue to enter into license agreements to access and utilize certain technology. We evaluate if the license agreement results in the acquisition of an asset or a business and then determine if the acquired asset has the ability to generate revenues or is subject to regulatory approval. When regulatory approval is not required, we record the license as an asset and amortize it over the estimated economic life. When regulatory approval is required, we record the amount paid as a research and development expense.

Income taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Significant judgment is required in determining the net valuation allowance which includes our evaluation of all available evidence including past operating results, estimates on future taxable income and acquisition-related tax assets and liabilities.

We historically established a full valuation allowance against our deferred tax assets due to the uncertainty surrounding realization of such assets. In 2021, we released approximately \$37.2 million of our valuation allowance to account for acquired intangibles that support the future realization of some of our deferred tax assets. Due to the overall increase of deferred tax assets, our valuation allowance has also increased from the prior year.

Stock-based compensation

We measure stock-based payment awards made to employees and directors based on the estimated fair values of the awards and recognize the compensation expense over the requisite service period. We use the Black-Scholes option-pricing model to estimate the fair value of stock option awards and ESPP purchases. The fair value of RSU awards with time-based vesting terms is based on the grant date share price. We grant PRSU awards to certain employees, which vest upon the achievement of certain performance conditions subject to the employees' continued service relationship with us. The probability of vesting is assessed at each reporting period and compensation cost is adjusted based on this probability assessment. We recognize such compensation expense on an accelerated vesting method.

Stock-based compensation expense for awards without a performance condition is recognized using the straight-line method. Stock-based compensation expense is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, our stock-based compensation is reduced for estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

We account for stock issued in connection with business combinations based on the fair value on the date of issuance.

Advertising

Advertising expenses are expensed as incurred. We incurred advertising expenses of \$20.2 million, \$11.4 million and \$9.9 million during the years ended December 31, 2021, 2020 and 2019, respectively.

Comprehensive loss

Comprehensive loss is composed of two components: net loss and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' equity, but are excluded from net loss. Our other comprehensive income (loss) consists of unrealized gains or losses on investments in available-for-sale securities.

Net loss per share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury stock method. Potentially dilutive securities, consisting of preferred stock, options to purchase common stock, common stock warrants, shares of common stock pursuant to ESPP, common stock issuable in connection with our Convertible Senior Notes, RSUs and PRSUs, are considered to be common stock equivalents and were excluded from the calculation of diluted net loss per share because their effect would be antidilutive for all periods presented.

Recent accounting pronouncements

We evaluate all ASUs issued by the FASB for consideration of their applicability. ASUs not included in the disclosures in this report were assessed and determined to be either not applicable or are not expected to have a material impact on our consolidated financial statements.

Recently issued accounting pronouncements not yet adopted

In October 2021, the FASB issued ASU 2021-08, *Business Combinations ("Topic 805"): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*. The amendments of this ASU require entities to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC Topic 606, *Revenue from Contracts with Customers*. At the acquisition date, an acquirer should account for the related revenue contracts in accordance with ASC Topic 606 as if it had originated the contracts. The amendments improve comparability after the business combination by providing consistent recognition and measurement guidance for revenue contracts with customers acquired in a business combination and revenue contracts with customers not acquired in a business combination. The amendments in this update should be applied prospectively and are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. We do not expect the adoption of this standard to have a material impact on our consolidated financial statements and related disclosures.

Recently adopted accounting pronouncements

In August 2020, the FASB issued ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for certain convertible instruments, amends the guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. This new standard is effective for our interim and annual periods beginning January 1, 2022, and earlier adoption is permitted. We elected to adopt the amendments on a modified retrospective basis effective January 1, 2021, which required a cumulative-effect adjustment to retained earnings. The cumulative-effect adjustment resulted in a decrease in accumulated deficit of \$17.0 million related to the reversal of the equity component and associated issuance costs as well as adjustment of the related amortization costs of our convertible senior notes due 2024. Reporting periods beginning on or after January 1, 2021 are presented under this new guidance while prior periods have not been adjusted and continue to be reported in accordance with our historic accounting under U.S. GAAP. See further information about our Convertible Senior Notes in Note 8, "Commitments and contingencies."

3. Revenue, accounts receivable and deferred revenue

Test revenue is generated from sales of diagnostic tests and precision oncology products to four groups of customers: biopharmaceutical partners; patients who pay directly; patients' insurance carriers; and other business-to-business customers (e.g., hospitals, clinics, medical centers). Test revenue is generated in two ways: through a centralized lab and decentralized through the shipment of reactions to biopharmaceutical partners and other business-to-business customers. We refer to the set of reagents needed to perform a next-generation sequencing test as a "reaction." Amounts billed and collected, and the timing of collections, vary based on the type of payer. Other revenue consists principally of revenue recognized under contracts for biopharmaceutical development services and other collaboration and genome network agreements and is accounted for under the provisions provided in ASC Topic 606.

Our revenue as disaggregated by payer category and revenue subtype is as follows (in thousands):

	Patient		Biopharma partner	Other business-to-business	Year Ended December 31, 2021
	Insurance	Direct			
Test revenue:					
Centralized	\$ 276,916	\$ 41,668	\$ 40,181	\$ 48,696	\$ 407,461
Decentralized	—	—	1,278	35,333	36,611
Total test revenue	276,916	41,668	41,459	84,029	444,072
Other revenue	—	—	11,578	4,799	16,377
Total revenue	\$ 276,916	\$ 41,668	\$ 53,037	\$ 88,828	\$ 460,449

	Patient		Biopharma partner	Other business-to-business	Year Ended December 31, 2021
	Insurance	Direct			
Test revenue:					
Centralized	\$ 181,026	\$ 23,972	\$ 26,228	\$ 32,736	\$ 263,962
Decentralized	—	—	837	7,511	8,348
Total test revenue	181,026	23,972	27,065	40,247	272,310
Other revenue	—	—	4,488	2,800	7,288
Total revenue	\$ 181,026	\$ 23,972	\$ 31,553	\$ 43,047	\$ 279,595

	Patient		Biopharma partner	Other business-to-business	Year Ended December 31, 2021
	Insurance	Direct			
Test revenue:					
Centralized	\$ 153,827	\$ 17,597	\$ 10,876	\$ 30,173	\$ 212,473
Total test revenue	153,827	17,597	10,876	30,173	212,473
Other revenue	—	—	2,077	2,274	4,351
Total revenue	\$ 153,827	\$ 17,597	\$ 12,953	\$ 32,447	\$ 216,821

We recognize revenue related to billings based on estimates of the amount that will ultimately be realized. Cash collections for certain tests delivered may differ from rates originally estimated. As a result of new information, we update our estimate quarterly of the amounts to be recognized for previously delivered tests which resulted in the following increases to revenue and decreases to our loss from operations and basic and diluted net loss per share (in millions, except per share amounts):

	Year Ended December 31,		
	2021	2020	2019
Revenue	\$ 13.5	\$ 4.4	\$ 4.1
Loss from operations	\$ (13.5)	\$ (4.4)	\$ (4.1)
Net loss per share, basic and diluted	\$ (0.06)	\$ (0.03)	\$ (0.05)

The increase in revenue from previously delivered tests for the year ended December 31, 2021 as compared to the same period in 2020 and 2019, respectively, was primarily due to increased billable volumes during 2021 and higher average revenue per test across all test categories when compared to initial estimates.

Impact of COVID-19

Our daily test volumes have recovered from the low in March 2020, although the ongoing COVID-19 pandemic continues to impact our business operations and practices. While we expect that it may continue to impact our business, we experienced limited disruption during 2021. We have reviewed and adjusted for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

Approximately 8% of our workforce as of March 31, 2020 was impacted by a reduction in force in April 2020 in an initiative to manage costs and cash burn that resulted in one-time costs in the second quarter of 2020 of \$3.8 million. In addition, effective May 2020, we reduced the salaries of our named executive officers by approximately 20%, which reductions ceased as of January 2021.

In March 2020, the CARES Act was signed into law as a stimulus bill intended to bolster the economy, among other things, and provide assistance to qualifying businesses and individuals. The CARES Act included an infusion of funds into the healthcare system. In April 2020, we received \$3.8 million as a part of this initiative, and in January 2021, we received an additional \$2.3 million. These payments were recognized as other income (expense), net in our consolidated statements of operations during the periods received. At this time, we are not certain of the availability, extent or impact of any future relief provided under the CARES Act.

Accounts receivable

The majority of our accounts receivable represents amounts billed to biopharmaceutical partners and other business-to-business customers for test and other revenue recognized, and estimated amounts to be collected from third-party insurance payers for genetic testing revenue recognized. Also included are amounts due under the terms of collaboration and genome network agreements for diagnostic testing and data aggregation reporting services provided and proprietary platform access rights transferred.

We also record unbilled revenue for revenue recognized but yet to be billed for services provided to biopharmaceutical companies related to companion diagnostic development. This contract receivable was \$4.3 million as of both December 31, 2021 and 2020 and was included in prepaid expenses and other current assets on the consolidated balance sheets.

Deferred revenue

We record a contract liability when cash payments are received or due in advance of our performance related to one or more performance obligations. The deferred revenue balance primarily consists of advanced billings for biopharmaceutical development services, including billings at the initiation of a performance-based milestones, and recognized as revenue in the applicable future period when the revenue is earned. Also included are prepayments related to our consumer direct channel. We recognized revenue of \$2.9 million and \$1.4 million from deferred revenue for the year ended as of December 31, 2021 and 2020, respectively.

4. Business combinations

Singular Bio

In June 2019, we acquired 100% of the fully diluted equity of Singular Bio Inc. ("Singular Bio"), a privately held company developing single molecule detection technology, for approximately \$57.3 million, comprised of \$53.9 million in the form of 2.5 million shares of our common stock and the remainder in cash.

In June 2019, we granted approximately \$90.0 million of RSUs under our 2015 Stock Incentive Plan as inducement awards to new employees who joined Invitae in connection with our acquisition of Singular Bio. \$45.0 million of the RSUs are time-based and vested in three equal installments in December 2019, June 2020, and December 2020, subject to the employee's continued service with us ("Time-based RSUs"), and \$45.0 million of the RSUs are PRSUs that vest upon the achievement of certain performance conditions. Since the number of awards granted is based on a 30-day volume weighted-average share price with a fixed dollar value, these Time-based RSUs and PRSUs are liability-classified and the fair value is estimated at each reporting period based on the number of shares that are expected to be issued at each reporting date and our closing stock price, which combined are categorized as Level 3 inputs. Therefore, fair value of the RSUs and PRSUs and the number of shares to be issued are not fixed until the awards vest.

During the years ended December 31, 2021 and 2020, we recorded research and development stock-based compensation expense of nil and \$29.1 million, respectively, related to the Time-based RSUs, and \$1.2 million and \$19.4 million, respectively, related to the PRSUs based on our evaluations of the probability of achieving performance conditions. As of December 31, 2021, there was no remaining liability related to the Singular Bio transaction.

Jungla

In July 2019, we acquired 100% of the equity interest of Jungla Inc. ("Jungla"), a privately held company developing a platform for molecular evidence testing in genes, for approximately \$59.0 million, comprised of \$44.9 million in the form of shares of our common stock and the remainder in cash.

We may be required to pay contingent consideration based on achievement of post-closing development milestones. As of the acquisition date, the fair value of this contingent consideration was \$10.7 million, which includes cash and common stock. This fair value measurement is based on significant inputs not observable in the market and, therefore, represents a Level 3 measurement. The material factors that may impact fair value of the contingent consideration, and therefore, this liability, are the probabilities and timing of achieving the related milestones and the discount rate used to estimate fair value. Significant changes in any of the probabilities of success would result in a significant change in the fair value, which is estimated at each reporting date with changes reflected as change in fair value of contingent consideration. The remaining milestone was achieved in July 2021 and the fair value of the contingent consideration was reduced to nil as of December 31, 2021.

Diploid

In March 2020, we acquired 100% of the equity interest of Orbicule BV ("Diploid"), a developer of artificial intelligence software capable of diagnosing genetic disorders using sequencing data and patient information, for approximately \$82.3 million in cash and shares of our common stock. Of the stock purchase price consideration issued, approximately 0.4 million shares are subject to a hold-back to satisfy indemnification obligations that may arise. In September 2021, the amounts held back to satisfy indemnification obligations for Diploid were released in full to the former shareholders.

Genelex and YouScript

In April 2020, we acquired 100% of the equity interest of Genelex Solutions, LLC ("Genelex") and YouScript Incorporated ("YouScript") to bring pharmacogenetic testing and integrated clinical decision support to Invitae. We acquired Genelex for approximately \$13.2 million, primarily in shares of our common stock. Of the stock purchase price consideration issued, approximately 0.1 million shares were subject to a hold-back to satisfy indemnification obligations that may arise. We acquired YouScript for approximately \$52.7 million, including cash consideration of \$24.5 million and the remainder in shares of our common stock. Of the purchase price consideration for YouScript, approximately \$1.4 million and 0.5 million shares of our common stock are subject to a hold-back to satisfy indemnification obligations that may arise.

As of the acquisition date, we recorded stock payable liabilities of \$6.2 million to represent the hold-back obligation to issue shares subject to indemnification claims that may arise. In April 2021, the amounts held back to satisfy indemnification obligations for Genelex were released in full to the former shareholders. As of December 31,

2021, the value of these liabilities were \$3.5 million related to YouScript with the \$15.4 million change in fair value year over year recorded in other income (expense), net.

We may be required to pay contingent consideration in the form of additional shares of our common stock in connection with the acquisition of Genelex if, within a specified period following the closing, we achieve a certain product milestone, in which case we would issue shares of our common stock with a value equal to a portion of the gross revenues actually received by us for a pharmacogenetic product reimbursed through certain payers during an earn-out period of up to four years. As of the acquisition date, the fair value of this contingent consideration was \$2.0 million. This fair value measurement is based on significant inputs not observable in the market and, therefore, represents a Level 3 measurement. The material factors that may impact the fair value of the contingent consideration, and therefore, this liability, are the probabilities and timing of achieving the related milestone, the estimated revenues achieved for a pharmacogenetic product and the discount rate used to estimate the fair value. Significant changes in any of the probabilities of success would result in a significant change in the fair value, which is estimated at each reporting date. As of December 31, 2021, the fair value of this contingent consideration was \$1.9 million.

ArcherDX

In October 2020, we acquired ArcherDX Inc. ("ArcherDX"), a genomics analysis company democratizing precision oncology. Under the terms of the agreement, we acquired ArcherDX for upfront consideration consisting of 30.0 million shares of our common stock and \$325.0 million in cash, plus up to an additional 27.0 million shares of our common stock payable in connection with the achievement of certain milestones. During the three months ended March 31, 2021, Invitae and the sellers of ArcherDX reached an agreement to reduce the purchase price by \$1.2 million based on the final acquired net working capital. This adjustment was recorded during the three months ended March 31, 2021 and reduced the contingent consideration liability and goodwill by approximately \$1.2 million.

We were required to pay contingent consideration based on achievement of post-closing development and revenue milestones. As of the acquisition date, the total fair value of the contingent consideration was \$945.2 million. Of the five milestones, one milestone was achieved in November 2020, which resulted in the issuance of 5.0 million shares of our common stock and a cash payment of \$1.9 million, and three milestones were achieved or deemed to be achieved during the three months ended June 30, 2021, which resulted in the issuance of 13.8 million shares of our common stock and a cash payment of \$3.3 million in July 2021. The remaining milestone is based upon receiving FDA clearance or approval of a therapy selection IVD, which per the terms of the acquisition agreement, must be completed by March 31, 2022, subject to certain extensions (the "ArcherDX Final Milestone"). The material factors that may impact the fair value of the contingent consideration, and therefore the liability, are (i) the estimated number of shares to be issued, (ii) the volatility of our common stock, (iii) the probabilities of achievement of milestones within the timeframes prescribed in the acquisition agreement and (iv) discount rates, all of which are Level 3 inputs not supported by market activity. Significant changes in any of these inputs may result in a significant change in fair value, which is estimated at each reporting date. As of December 31, 2020, the fair value of the contingent consideration representing the remaining milestones was \$788.3 million. With respect to the ArcherDX Final Milestone, the liability was reduced to nil as of June 30, 2021 from \$262.5 million as of March 31, 2021 and \$287.7 million as of December 31, 2020, with the offsetting change recorded as changes in fair value of contingent consideration in our consolidated statements of operations. The removal of the liability balance and the associated change in fair value of contingent consideration was a result of our reassessment of the steps necessary to achieve clearance or approval based on FDA feedback received principally in the three months ended June 30, 2021. As a result of our reassessment, we do not believe achievement of the conditions will occur within the specified timeframe prescribed in the acquisition agreement. We expect FDA clearance or approval of a therapy selection IVD at a later date subject to resolution of the necessary steps.

In connection with the acquisition, we granted awards of common stock to new employees who joined Invitae in connection with our acquisition of ArcherDX that vest upon the achievement of the contingent consideration milestones discussed above and are subject to the employees' continued service with us, unless terminated without cause in which case vesting is only dependent on milestone achievement. As the number of shares that are expected to be issued are fixed, the awards are equity-classified. During the year ended December 31, 2021, we recorded a net \$41.8 million in stock-based compensation expense related to the ArcherDX milestones, which includes \$38.5 million related to milestones achieved in prior periods, \$33.0 million due to an accounting modification of certain awards whereby the employees' continued substantive services were no longer required, offset by a reversal of \$29.7 million recognized in prior periods related to the determination that the ArcherDX Final Milestone will not be achieved within the specified timeframe prescribed in the acquisition agreement.

One Codex

In February 2021, we acquired 100% of the equity interest of Reference Genomics, Inc. d/b/a One Codex ("One Codex"), a company developing and commercializing products and services relating to microbiome sequencing, analysis and reporting, for upfront consideration consisting of \$17.3 million in cash and 1.4 million shares of our common stock, of which approximately 0.2 million shares are subject to a hold-back to satisfy indemnification obligations that may arise following the closing. These shares subject to a hold-back were issued to a third-party at the closing date to hold in escrow until the escrow period is complete, and as such were classified as equity. We included the financial results of One Codex in our consolidated financial statements from the acquisition date, which were not material.

The following table summarizes the purchase price and post-combination expense recorded as a part of the acquisition of One Codex (in thousands):

	Purchase Price	Post-combination Expense
Cash transferred	\$ 16,504	\$ 783
Hold-back consideration - common stock	8,113	359
Common stock transferred	58,774	2,600
Total	<u>\$ 83,391</u>	<u>\$ 3,742</u>

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by us. While we believe that our estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed through our acquisition of One Codex at the date of acquisition (in thousands):

Cash	\$ 1,549
Accounts receivable	684
Developed technology	23,841
Customer relationships	440
Total identifiable assets acquired	<u>26,514</u>
Other liabilities	(415)
Deferred tax liability	(6,150)
Net identifiable assets acquired	<u>19,949</u>
Goodwill	63,442
Total purchase price	<u>\$ 83,391</u>

Based on the guidance provided in ASC 805, we accounted for the acquisition of One Codex as a business combination and determined that 1) One Codex was a business that combines inputs and processes to create outputs, and 2) substantially all of the fair value of gross assets acquired was not concentrated in a single identifiable asset or group of similar identifiable assets.

We measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill, which represent Level 3 fair value measurements. The intangible assets acquired were developed technology related to One Codex's microbiome and infectious disease platform and its customer relationships in place at time of acquisition. The fair value of the intangible assets was estimated using an income approach with an estimated useful life of nine years.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of One Codex resulted in the recognition of \$63.4 million of goodwill, which we believe relates primarily to expansion of the acquired technology to apply to new areas of genetic testing. The goodwill created as a result of the acquisition of One Codex is not deductible for tax purposes.

Genosity

In April 2021, we acquired 100% of the fully diluted equity of Genosity Inc. ("Genosity"), a company providing genomic laboratory services, for approximately \$196.0 million, consisting of approximately \$120.0 million in cash and 1.9 million shares of our common stock. In connection with this transaction, we granted RSUs having a value of up to \$5.0 million to certain continuing employees and recognized \$0.8 million in stock-based compensation expense for

the year ended December 31, 2021. We included the financial results of Genosity in our consolidated financial statements from the acquisition date, which were not material.

The following table summarizes the purchase price recorded as a part of the acquisition of Genosity (in thousands):

	<u>Purchase Price</u>	
Cash transferred	\$	119,959
Hold-back and other consideration		8,774
Common stock transferred		67,308
Total	\$	<u>196,041</u>

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by us. While we believe that our estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed through our acquisition of Genosity at the date of acquisition (in thousands):

Cash	\$	906
Accounts receivable		355
Developed technology		76,500
Other assets		3,732
Total identifiable assets acquired		<u>81,493</u>
Other liabilities		(2,852)
Deferred tax liability		<u>(17,600)</u>
Net identifiable assets acquired		61,041
Goodwill		135,000
Total purchase price	\$	<u>196,041</u>

Based on the guidance provided in ASC 805, we accounted for the acquisition of Genosity as a business combination and determined that 1) Genosity was a business that combines inputs and processes to create outputs, and 2) substantially all of the fair value of gross assets acquired was not concentrated in a single identifiable asset or group of similar identifiable assets. Pursuant to the terms of the acquisition, a provision was incorporated to provide additional shares in the event that our common stock share price decreased after the acquisition, but prior to filing a resale registration statement. At the time of the acquisition, we estimated this provision to be \$7.0 million. On filing the resale registration statement during the period ended June 30, 2021, the fair value was \$3.2 million; the difference of \$3.8 million was recorded in general and administrative expense.

Our purchase price allocation for the acquisition is preliminary and subject to revision as additional information about fair value of assets and liabilities becomes available, primarily related to our deferred tax liability assumed in connection with the acquisition. Additional information that existed as of the acquisition date but at the time was unknown to us may become known to us during the remainder of the measurement period, a period not to exceed 12 months from the acquisition date.

We measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill, which represent Level 3 fair value measurements. The intangible assets acquired were developed technology related to Genosity's genomic laboratory services and sequencing software in place at the time of acquisition. The fair value of the intangible assets was estimated using an income approach with an estimated useful life of 12 years.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Genosity resulted in the recognition of \$135.0 million of goodwill, which we believe relates primarily to expansion of the acquired technology to apply to new areas of genetic testing. The goodwill created as a result of the acquisition of Genosity is not deductible for tax purposes.

Ciitizen

In September 2021, we acquired 100% of the equity of Ciitizen Corporation ("Ciitizen"), a patient-centric health technology company, for approximately \$308.3 million, consisting of approximately \$87.4 million in cash and 6.3 million shares of our common stock, of which approximately \$10.4 million in cash and 0.8 million shares are

subject to a hold-back to satisfy indemnification obligations that may arise following the closing. As of December 31, 2021, the value of the stock payable liability was \$12.1 million with the \$10.6 million change recorded in other income (expense), net. In connection with this transaction, we granted RSUs having a value of up to \$246.9 million to certain continuing employees. For the year ended December 31, 2021, we recorded stock-based compensation expense of \$24.4 million primarily in research and development expense. We included the financial results of Ciitizen in our consolidated financial statements from the acquisition date, which were not material.

The following table summarizes the purchase price recorded as a part of the acquisition of Ciitizen (in thousands):

	<u>Purchase Price</u>
Cash transferred	\$ 87,361
Hold-back and other consideration	34,161
Common stock transferred	186,778
Total	<u>\$ 308,300</u>

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by us. While we believe that our estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed through our acquisition of Ciitizen at the date of acquisition (in thousands):

Cash	\$ 274
Accounts receivable	748
Other receivables	688
Developed technology	92,900
Other assets	970
Total identifiable assets acquired	<u>95,580</u>
Other liabilities	(2,550)
Deferred tax liability	(6,900)
Net identifiable assets acquired	<u>86,130</u>
Goodwill	222,170
Total purchase price	<u>\$ 308,300</u>

Based on the guidance provided in ASC 805, we accounted for the acquisition of Ciitizen as a business combination and determined that 1) Ciitizen was a business that combines inputs and processes to create outputs, and 2) substantially all of the fair value of gross assets acquired was not concentrated in a single identifiable asset or group of similar identifiable assets.

Our purchase price allocation for the acquisition is preliminary and subject to revision as additional information about fair value of assets and liabilities becomes available, primarily related to certain aspects of our deferred tax liability assumed in connection with the acquisition. Additional information that existed as of the acquisition date but at the time was unknown to us may become known to us during the remainder of the measurement period, a period not to exceed 12 months from the acquisition date.

We measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill, which represent Level 3 fair value measurements. The intangible asset acquired were developed technology related to Ciitizen's patient data platform. The fair value of the intangible assets was estimated using an income approach with an estimated useful life of 12 years.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Ciitizen resulted in the recognition of \$222.2 million of goodwill, which we believe relates primarily to expansion of the acquired technology to apply to new areas of patient-centric consumer health tech company. The goodwill created as a result of the acquisition of Ciitizen is not deductible for tax purposes.

5. Goodwill and intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows (in thousands):

Balance as of December 31, 2020	\$ 1,863,623
Goodwill adjustment	(1,176)
Goodwill acquired	420,612
Balance as of December 31, 2021	<u>\$ 2,283,059</u>

Intangible assets

The following table presents details of our acquired intangible assets as of December 31, 2021 (in thousands):

	Cost	Accumulated Amortization	Net	Weighted-Average Useful Life (in Years)	Weighted-Average Estimated Remaining Useful Life (in Years)
Customer relationships	\$ 41,515	\$ (13,096)	\$ 28,419	10.8	7.8
Developed technology	662,106	(81,902)	580,204	10.2	9.1
Non-compete agreement	286	(286)	—	0.0	0.0
Tradename	21,085	(2,207)	18,878	12.0	10.8
Patent licensing agreement	495	(136)	359	15.0	10.9
Right to develop new technology	19,359	(1,613)	17,746	15.0	13.8
In-process research and development	542,388	—	542,388	n/a	n/a
	<u>\$ 1,287,234</u>	<u>\$ (99,240)</u>	<u>\$ 1,187,994</u>	10.4	9.2

Acquisition-related intangibles included in the above table are generally finite-lived, other than in-process research and development, which has an indefinite life, and are carried at cost less accumulated amortization. Customer relationships related to our 2017 business combinations are being amortized on an accelerated basis in proportion to estimated cash flows. All other finite-lived acquisition-related intangibles are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized. Amortization expense was \$58.8 million, \$26.6 million, and \$7.7 million for the years ended December 31, 2021, 2020 and 2019, respectively. Amortization expense is recorded to cost of revenue, research and development, sales and marketing and general and administrative expense.

The following table summarizes our estimated future amortization expense of intangible assets with finite lives as of December 31, 2021 (in thousands):

2022	\$ 73,706
2023	72,693
2024	72,414
2025	70,661
2026	70,627
Thereafter	285,505
Total estimated future amortization expense	<u>\$ 645,606</u>

In December 2021, we acquired 100% of the equity interest of Stratify Genomics Inc., a cancer risk stratification company, for \$29.0 million consisting of 1.0 million shares of common stock, \$4.2 million in assumed liabilities, and \$8.0 million in cash. We accounted for this transaction as an asset acquisition, as substantially all of the fair value is concentrated in the developed technology acquired. As goodwill is not recorded under an asset acquisition, an \$8.7 million deferred tax liability arising from book/tax basis differences increased the value of the assets acquired above the purchase price. As a result, the fair value of the developed technology is \$37.5 million, which will be amortized over eight years to cost of revenue. The remaining purchase price of \$0.2 million is the fair value of cash and cash equivalents.

In July 2021, we acquired 100% of the equity interest of Medneon LLC, a digital health artificial intelligence company, for \$34.1 million consisting of 0.4 million shares of common stock, \$4.9 million in assumed liabilities, and \$12.9 million in cash. We accounted for this transaction as an asset acquisition, as substantially all of the fair value is concentrated in the developed technology acquired. The fair value of the developed technology is \$33.9 million, which will be amortized over eight years to cost of revenue. The remaining purchase price of \$0.2 million is the fair value of cash and cash equivalents.

In December 2020, we entered into an agreement to acquire technology focused on informing clinical decisions for \$2.9 million. We accounted for this transaction as an asset acquisition of developed technology, which will be amortized over eight years to research and development expense.

6. Balance sheet components

Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2021	2020
Raw materials	\$ 27,178	\$ 21,324
Work in progress	5,342	8,847
Finished goods	996	1,859
Total inventory	<u>\$ 33,516</u>	<u>\$ 32,030</u>

Property and equipment, net

Property and equipment consisted of the following (in thousands):

	December 31,	
	2021	2020
Leasehold improvements	\$ 31,159	\$ 26,516
Laboratory equipment	61,317	45,342
Computer equipment	15,452	10,939
Furniture and fixtures	2,130	1,967
Construction-in-progress	52,039	12,061
Other	925	624
Total property and equipment, gross	<u>163,022</u>	<u>97,449</u>
Accumulated depreciation and amortization	(48,308)	(31,347)
Total property and equipment, net	<u>\$ 114,714</u>	<u>\$ 66,102</u>

Depreciation expense was \$18.1 million, \$10.5 million and \$7.1 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2021	2020
Accrued compensation and related expenses	\$ 35,877	\$ 25,221
Accrued expenses	32,136	14,933
Compensation and other liabilities associated with business combinations	11,622	25,600
Deferred revenue	9,431	6,378
Accrued interest	6,646	2,333
Other accrued liabilities	10,741	11,593
Total accrued liabilities	<u>\$ 106,453</u>	<u>\$ 86,058</u>

Other long-term liabilities

Other long-term liabilities consisted of the following (in thousands):

	December 31,	
	2021	2020
Compensation and other liabilities associated with business combinations, non-current	\$ 27,919	\$ 825,976
Deferred revenue, non-current	663	1,380
Other	9,215	13,900
Total other long-term liabilities	\$ 37,797	\$ 841,256

7. Fair value measurements

Financial assets and liabilities are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The authoritative guidance establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques is summarized as follows:

Level 1—Observable inputs such as quoted prices (unadjusted) for identical instruments in active markets.

Level 2—Observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-derived valuations whose significant inputs are observable.

Level 3—Unobservable inputs that reflect the reporting entity's own assumptions.

The following tables set forth the fair value of our consolidated financial instruments that were measured at fair value on a recurring basis (in thousands):

	December 31, 2021						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	\$ 913,990	\$ —	\$ —	\$ 913,990	\$ 913,990	\$ —	\$ —
U.S. Treasury notes	111,187	—	(6)	111,181	111,181	—	—
U.S. government agency securities	10,941	—	(1)	10,940	—	10,940	—
Total financial assets	\$ 1,036,118	\$ —	\$ (7)	\$ 1,036,111	\$ 1,025,171	\$ 10,940	\$ —
Financial liabilities:							
Stock payable liability				\$ 20,925	\$ —	\$ —	\$ 20,925
Contingent consideration				1,875	—	—	1,875
Total financial liabilities				\$ 22,800	\$ —	\$ —	\$ 22,800

	December 31, 2021
Reported as:	
Cash equivalents	\$ 903,715
Restricted cash	10,275
Marketable securities	122,121
Total cash equivalents, restricted cash, and marketable securities	\$ 1,036,111
Other long-term liabilities	\$ 22,800

	December 31, 2020						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	\$ 83,109	\$ —	\$ —	\$ 83,109	\$ 83,109	\$ —	\$ —
U.S. Treasury notes	164,894	7	(15)	164,886	164,886	—	—
U.S. government agency securities	64,291	9	—	64,300	—	64,300	—
Total financial assets	<u>\$ 312,294</u>	<u>\$ 16</u>	<u>\$ (15)</u>	<u>\$ 312,295</u>	<u>\$ 247,995</u>	<u>\$ 64,300</u>	<u>\$ —</u>
Financial liabilities:							
Stock payable liability				\$ 39,237	\$ —	\$ —	\$ 39,237
Contingent consideration				\$ 796,639	\$ —	\$ —	\$ 796,639
Total financial liabilities				<u>\$ 835,876</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 835,876</u>

	December 31, 2020	
Reported as:		
Cash equivalents	\$	76,000
Restricted cash		6,000
Marketable securities		229,000
Total cash equivalents, restricted cash, and marketable securities	<u>\$</u>	<u>312,000</u>
Accrued liabilities	\$	10,000
Other long-term liabilities		825,000
Total liabilities	<u>\$</u>	<u>835,000</u>

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. The total fair value of investments with unrealized losses at December 31, 2021 was \$122.1 million. Our debt securities of U.S. government agencies are classified as Level 2 as they are valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to benchmark yields, interest rate curves, reported trades, broker/dealer quotes and reference data. None of the available-for-sale securities held as of December 31, 2021 have been in an unrealized loss position for more than one year. At December 31, 2021, the remaining contractual maturities of available-for-sale securities ranged from zero to three months. Interest income generated from our investments was \$6.9 million and \$4.0 million during the years ended December 31, 2021 and 2020, respectively.

Stock payable liabilities relate to certain indemnification hold-backs resulting from business combinations that are settled in shares of our common stock. We elected to account for these liabilities using the fair value option due to the inherent nature of the liabilities and the changes in value of the underlying shares that will ultimately be issued to settle the liabilities. The estimated fair value of these liabilities is classified as Level 3 and determined based upon the number of shares that are issuable to the sellers and the quoted closing price of our common stock as of the reporting date. The number of shares that will ultimately be issued is subject to adjustment for indemnified claims that existed as of the closing date for each acquisition. Changes in the number of shares issued and share price can significantly affect the estimated fair value of the liabilities. During the year ended December 31, 2021, the change in fair value related to stock payable liabilities recorded to other income (expense), net was expense of \$25.2 million.

8. Commitments and contingencies

Leases

In 2015, we entered into an operating lease agreement for our headquarters and main production facility in San Francisco, California which commenced in 2016. This lease expires in 2026 and we may renew the lease for an additional ten years. This optional period was not considered reasonably certain to be exercised and therefore we

determined the lease term to be a ten-year period expiring in 2026. In connection with the execution of the lease, we provided a security deposit of approximately \$4.6 million which is included in restricted cash in our consolidated balance sheets. We also have other operating leases for office and laboratory space domestically and internationally. We expect to enter into new leases and modify existing leases as we support continued growth of our operations.

We have entered into various finance lease agreements to obtain laboratory equipment. The terms of our finance leases are generally three years and are typically secured by the underlying equipment. The portion of the future payments designated as principal repayment and related interest was classified as a finance lease obligation on our consolidated balance sheets. Finance lease assets are recorded within other assets on our consolidated balance sheets.

Supplemental information regarding our operating and finance leases were as follows:

	Year Ended December 31,	
	2021	2020
Weighted-average remaining lease term:		
Operating leases	9.0 years	5.4 years
Finance leases	2.4 years	2.6 years
Weighted-average discount rate:		
Operating leases	7.0 %	10.6 %
Finance leases	7.2 %	4.8 %
Cash payments included in the measurement of lease liabilities (in millions):		
Operating leases	\$ 18.3	\$ 11.6
Finance leases	\$ 2.9	\$ 2.0

The components of lease costs, which were included in cost of revenue, research and development, selling and marketing and general and administrative expenses on our consolidated statements of operations, were as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Operating lease costs	\$ 21,151	\$ 11,329	\$ 10,329
Sublease income	—	—	(173)
Finance lease costs:			
Amortization of right-of-use assets	3,488	2,084	1,546
Interest on lease liabilities	496	—	—
Total lease costs	\$ 25,135	\$ 13,413	\$ 11,702

Future payments under operating and finance leases as of December 31, 2021 are as follows (in thousands):

	Operating leases	Finance leases
2022	\$ 18,470	\$ 4,719
2023	23,108	4,133
2024	28,000	1,758
2025	26,647	177
2026	24,031	—
Thereafter	80,464	—
Future non-cancelable minimum lease payments	200,720	10,787
Less: interest	(63,992)	(948)
Total lease liabilities	136,728	9,839
Less: current portion	(12,359)	(4,156)
Lease obligations, net of current portion	\$ 124,369	\$ 5,683

Debt financing

In November 2018, we entered into a Note Purchase Agreement (the "2018 Note Purchase Agreement") pursuant to which we were eligible to borrow an aggregate principal amount up to \$200.0 million over a seven year maturity term which included an initial borrowing of \$75.0 million in November 2018.

In September 2019, we settled our obligations under the 2018 Note Purchase Agreement in full for \$85.7 million, which included repayment of principal of \$75.0 million, accrued interest of \$2.4 million, and prepayment fees of \$8.9 million which were recorded as debt extinguishment costs in other expense, net in our consolidated statement of operations during the year ended December 31, 2019.

In October 2020, we entered into a credit agreement with a financial institution under which we borrowed \$135.0 million (the "2020 Term Loan") concurrent with the closing of the ArcherDX acquisition. The 2020 Term Loan is secured by a first priority lien on all of our and our subsidiaries' assets, and is guaranteed by us and our subsidiaries. The 2020 Term Loan bears interest at an annual rate equal to three-month LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75%. If three-month LIBOR can no longer be determined or if the applicable governmental authority ceases to supervise or sanction such rates, then we will endeavor to agree with the administrative agent, an alternate rate of interest that gives due consideration to the then prevailing market convention for determining interest for comparable loans in the United States, provided that until such alternative rate of interest is agreed, the 2020 Term Loan shall bear interest at the *Wall Street Journal* Prime Rate. The three-month LIBOR is expected to be available and representative through June 30, 2023. The 2020 Term Loan will mature on (i) June 1, 2024 if at such time our 2024 Notes (defined below) are outstanding and are due to mature on September 1, 2024 (provided that if, prior to such date, the maturity date of at least 80% of the 2024 Notes is extended to a date that is prior to September 1, 2025 the maturity date for the 2020 Term Loan will be automatically extended to a date that is 90 days prior to such 2024 Notes maturity date as extended), or (ii) otherwise, on June 1, 2025. The full amount of the 2020 Term Loan is due upon maturity. If the 2020 Term Loan is prepaid (whether such prepayment is optional or mandatory), we must pay a prepayment fee of 6% if the prepayment occurs prior to the third anniversary of the closing date or 4% if the prepayment occurs after the third anniversary of the closing date and we must also pay a make-whole fee if the prepayment occurs prior to the second anniversary of the closing date. In connection with the 2020 Term Loan, we issued warrants to purchase 1.0 million shares of our common stock with an exercise price of \$16.85 per share, exercisable through October 2027. The warrants, which were classified as equity, were recorded at an amount based on the allocated proceeds and do not require subsequent remeasurement. In October 2020, these warrants were exercised in full through net settlement resulting in the issuance of 0.7 million shares.

The credit agreement contains customary events of default and covenants, including among others, covenants limiting our ability to incur debt, incur liens, undergo a change in control, merge with or acquire other entities, make investments, pay dividends or other distributions to holders of our equity securities, repurchase stock, and dispose of assets, in each case subject to certain customary exceptions. In addition, the credit agreement contains financial covenants that require us to maintain a minimum cash balance and minimum quarterly revenue levels.

Debt discounts, including debt issuance costs, related to the 2020 Term Loan of \$32.8 million were recorded as a direct deduction from the debt liability and are being amortized to interest expense over the term of the 2020 Term Loan. Interest expense related to our debt financings, excluding the impact of our convertible senior notes, was \$23.7 million, \$7.4 million and \$5.7 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Convertible Senior Notes

Convertible senior notes due 2024

In September 2019, we issued, at par value, \$350.0 million aggregate principal amount of 2.00% convertible senior notes due 2024 (the "2024 Notes") in a private offering. The 2024 Notes are our senior unsecured obligations and will mature on September 1, 2024, unless earlier converted, redeemed or repurchased. The 2024 Notes bear cash interest at a rate of 2.0% per year, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on March 1, 2020.

Upon conversion, the 2024 Notes will be convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate for the 2024 Notes is 33.6293 shares of our common stock per \$1,000 principal amount of the 2024 Notes (equivalent to an initial conversion price of approximately \$29.74 per share of common stock).

If we undergo a fundamental change (as defined in the indenture governing the 2024 Notes), the holders of the 2024 Notes may require us to repurchase all or any portion of their 2024 Notes for cash at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased plus accrued and unpaid interest to, but excluding, the redemption date.

The 2024 Notes will be convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding March 1, 2024, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on December 31, 2019 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive)

during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2024 Notes on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per \$1,000 principal amount of 2024 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (3) if we call any or all of the 2024 Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or (4) upon the occurrence of specified corporate events. On or after March 1, 2024 until the close of business on the business day immediately preceding the maturity date, holders may convert their 2024 Notes at any time, regardless of the foregoing circumstances. These notes were convertible at the option of the holders during the quarters beginning on January 1, 2021 and April 1, 2021 due to the sale price of our common stock during the quarter ended December 31, 2020 and March 31, 2021, respectively. No holders converted their notes during the twelve months ended December 31, 2021.

We may not redeem the 2024 Notes prior to September 6, 2022. We may redeem for cash all or any portion of the 2024 Notes, at our option, on or after September 6, 2022 and on or before the 30th scheduled trading day immediately before the maturity date if the last reported sale price of the common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

Convertible senior notes due 2028

In April 2021, we issued, at 99% of par value, \$1,150.0 million aggregate principal amount of 1.5% convertible senior notes due 2028 (the "2028 Notes") in a private offering. The 2028 Notes are our senior unsecured obligations and will mature on April 1, 2028, unless earlier converted, redeemed or repurchased. The 2028 Notes bear cash interest at a rate of 1.5% per year, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on October 1, 2021. Upon conversion, the 2028 Notes will be convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

The 2028 Notes will be convertible at the option of the holder at any time until the second scheduled trading day prior to the maturity date, including in connection with a redemption by us. The 2028 Notes will be convertible into shares of our common stock based on an initial conversion rate of 23.1589 shares of common stock per \$1,000 principal amount of the 2028 Notes (which is equal to an initial conversion price of \$43.18 per share), in each case subject to customary anti-dilution and other adjustments as a result of certain extraordinary transactions.

We may not redeem the 2028 Notes prior to April 6, 2025. On or after April 6, 2025, the 2028 Notes will be redeemable by us in the event that the closing sale price of our common stock has been at least 150% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide the redemption notice at a redemption price of 100% of the principal amount of such 2028 Notes, plus accrued and unpaid interest to, but excluding, the redemption date.

With certain exceptions, upon a change of control of the Company or the failure of our common stock to be listed on certain stock exchanges, the holders of the 2028 Notes may require that we repurchase all or part of the principal amount of the Notes at a repurchase price of 100% of the principal amount of the 2028 Notes to be repurchased, plus unpaid interest to, but excluding, the maturity date.

Convertible senior notes

We adopted the provisions of ASU 2020-06 on January 1, 2021; see further information in Note 2, "Summary of significant accounting policies." Our Convertible Senior Notes consisted of the following (in thousands):

	December 31,	
	2021	2020
Outstanding principal	\$ 1,499,996	\$ 350,000
Unamortized debt discount and issuance costs	(35,858)	(66,276)
Net carrying amount, liability component	<u>\$ 1,464,138</u>	<u>\$ 283,724</u>

As of December 31, 2021, the fair value of the 2024 Notes and 2028 Notes was \$325.6 million and \$1.2 billion, respectively. The estimated fair value of the 2024 Notes and 2028 Notes, which use Level 2 fair value inputs, was determined based on the estimated or actual bid prices in an over-the-counter market and/or market conditions

including the price and volatility of our common stock and comparable company information. We recognized \$24.9 million and \$22.0 million of interest expense related to our convertible senior notes during the years ended December 31, 2021 and 2020, respectively. Of the interest expense recognized during the years ended December 31, 2021 and 2020, \$5.3 million and \$1.9 million, respectively, was related to amortization of issuance costs and the remainder was related to contractual interest incurred.

Other commitments

In the normal course of business, we enter into various purchase commitments primarily related to service agreements and laboratory supplies. At December 31, 2021, our total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were as follows (in thousands):

2022	25,893
2023	21,904
2024	7,367
2025	614
2026	—
Thereafter	—
Total	\$ 55,778

Guarantees and indemnification

As permitted under Delaware law and in accordance with our bylaws, we indemnify our directors and officers for certain events or occurrences while the officer or director is or was serving in such capacity. The maximum amount of potential future indemnification is unlimited; however, we maintain director and officer liability insurance. This insurance allows the transfer of the risk associated with our exposure and may enable us to recover a portion of any future amounts paid. We believe the fair value of these indemnification agreements is minimal. Accordingly, we did not record any liabilities associated with these indemnification agreements at December 31, 2021 or 2020.

Contingencies

We are and may from time to time be involved in various legal proceedings and claims arising in the ordinary course of business. Legal proceedings, including litigation, government investigations and enforcement actions could result in material costs, occupy significant management resources and entail civil and criminal penalties, even if we ultimately prevail. If an investigation results in a proceeding against us, an adverse outcome could include us being required to pay treble damages, and incur attorneys' fees, civil or criminal penalties and other adverse actions that could materially and adversely affect our business, financial condition and results of operations. While we believe any such claims are unsubstantiated, and we believe we are in compliance with applicable laws and regulations applicable to our business, the resolution of any such claims could be material.

We were not a party to any material legal proceedings at December 31, 2021, or at the date of this report except for matters listed below. We cannot currently predict the outcome of these actions.

Natera, Inc.

On January 27, 2020, Natera filed a lawsuit against ArcherDX (a subsidiary of Invitae effective October 2, 2020) in the United States District Court for the District of Delaware, alleging that ArcherDX's products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814. On March 25, 2020, ArcherDX filed an answer denying Natera's allegations and asserting certain affirmative defenses and counterclaims, including that U.S. Patent No. 10,538,814 is invalid and not infringed. On April 15, 2020, Natera filed an answer denying ArcherDX's counterclaims and filed an amended complaint alleging that ArcherDX's products using AMP chemistry, including our therapy selection IVDs, PCM, LiquidPlex, ArcherMET, FusionPlex, and VariantPlex, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, U.S. Patent No. 10,590,482, and U.S. Patent No. 10,597,708, each of which are held by Natera. Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of such patents. On May 13, 2020, ArcherDX filed an answer to Natera's amended complaint denying Natera's allegations and asserting certain affirmative defenses and counterclaims, including that the asserted patents are invalid and not infringed. On June 3, 2020, Natera filed an answer denying ArcherDX's counterclaims. On June 4, 2020, ArcherDX filed a motion seeking dismissal of Natera's infringement claims against our therapy selection IVDs, PCM, and ArcherMET, and for a judgment that U.S. Patent

No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On August 6, 2020, Natera filed another complaint against ArcherDX in the United States District Court for the District of Delaware alleging that ArcherDX's products using AMP chemistry, including our therapy selection IVDs, PCM, LiquidPlex, ArcherMET, and VariantPlex, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,731,220. Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of the patent. On October 13, 2020, the court issued an order denying ArcherDX's motion for dismissal of Natera's infringement claims against our therapy selection IVDs, PCM, and ArcherMET, and declined to enter judgment that U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On January 12, 2021, the court issued an order granting Natera leave to amend its complaint to add Invitae as a co-defendant and plead allegations that ArcherDX and Invitae induce end-users to infringe the patents-in-suit. Natera filed its Second Amended Complaint on the same day, with service completed on January 15, 2021. ArcherDX and Invitae filed answers to the Second Amended Complaint on January 26, 2021 and February 5, 2021, respectively, denying Natera's allegations and restating certain affirmative defenses and counterclaims of non-infringement and invalidity. The litigations have now been consolidated for all purposes. A claim construction order was issued on June 28, 2021. On October 27, 2021, Natera filed its Third Amended Complaint to add a Certificate of Correction to U.S. Patent No. 10,590,482. On November 3, 2021, ArcherDX filed its Answer and Counterclaims to Natera's Third Amended Complaint, adding an inequitable conduct defense and declaratory judgment counterclaims. Discovery concluded in December 2021. On January 21, 2022, Natera, ArcherDX and Invitae moved for summary judgment, wherein Natera seeks a determination on certain legal and equitable defenses and ArcherDX and Invitae seek a determination of non-infringement and invalidity of the asserted patents. Trial is scheduled for May 2022.

In addition, on October 6, 2020, Natera filed a complaint against Genosity in the United States District Court for the District of Delaware, alleging that Genosity's use of its AsTra products, and the manufacture, use, sale, and offer for sale of such products, infringes U.S. Patent No. 10,731,220. Natera's complaint further alleges that Genosity's accused products use ArcherDX's ctDNA and region-specific primers. Genosity filed an answer to the complaint on February 15, 2021, denying Natera's allegations and setting forth affirmative defenses and counterclaims of non-infringement, invalidity and unenforceability due to inequitable conduct. On March 8, 2021, Natera filed a motion to dismiss and strike certain affirmative defenses and counterclaims brought by Genosity relating to inequitable conduct; the court has not yet issued a decision. No case schedule has been set.

QIAGEN Sciences

On July 10, 2018, ArcherDX and the General Hospital Corporation d/b/a Massachusetts General Hospital, which we refer to as MGH, filed a lawsuit in the United States District Court for the District of Delaware against QIAGEN Sciences, LLC, QIAGEN LLC, QIAGEN Beverly, Inc., QIAGEN Gaithersburg, Inc., QIAGEN GmbH and QIAGEN N.V., which is collectively referred to herein as QIAGEN, and a named QIAGEN executive who was a former member of ArcherDX's board of directors, alleging several causes of action, including infringement of the '810 Patent, trade secret misappropriation, breach of fiduciary duty, false advertising, tortious interference and deceptive trade practices. The '810 Patent relates to methods for preparing a nucleic acid for sequencing and aspects of ArcherDX's AMP technology. On October 30, 2019, with the permission of the Court, ArcherDX amended ArcherDX's complaint to add a claim for infringement of the '597 Patent. The '597 Patent relates to methods of preparing and analyzing nucleic acids, such as by enriching target sequences prior to sequencing, and aspects of ArcherDX's AMP technology. The QIAGEN products that ArcherDX alleges infringe the '810 Patent and the '597 Patent include, but are not limited to, QIAseq Targeted DNA Panels, QIAseq Targeted RNAscan Panels, QIAseq Index Kits and QIAseq Immune Repertoire RNA Library Kits. ArcherDX is seeking, among other things, damages for ArcherDX's lost profits due to QIAGEN's infringement and a permanent injunction enjoining QIAGEN from marketing and selling the infringing products and from using ArcherDX's trade secrets. On December 5, 2019, QIAGEN and the named QIAGEN executive submitted their answer denying the allegations in ArcherDX's complaint and asserting affirmative defenses that, among other things, the '810 Patent and '597 Patent are not infringed by QIAGEN's products, that both patents are invalid, and that the complaint fails to state any claim for which relief may be granted. On March 1, 2021, each of ArcherDX and QIAGEN moved for summary judgment on issues relating to infringement and validity of ArcherDX's patents, breach of fiduciary duty and trade secret misappropriation. On June 18, 2021, ArcherDX informed the court that it would not assert the following claims to streamline the issues for trial: trade secret misappropriation, false advertising, deceptive trade practices, and tortious interference. The court denied QIAGEN's motion for summary judgment on trade secret misappropriation as moot on June 21, 2021, denied QIAGEN's motion for summary judgment on breach of fiduciary duty on July 26, 2021, and granted QIAGEN's motion for summary judgment of no literal infringement of the '810 Patent on August 21, 2021. Trial proceeded on August 23 through August 27, 2021, resulting in a unanimous jury verdict, which found that: (i) all asserted claims of the '810 and '597 Patents are valid, (ii) QIAGEN willfully infringed the asserted claims of the '810 patent (under the doctrine of equivalents) and the '597 patent (literal infringement), and (iii) ArcherDX and MGH are entitled to recover approximately \$4.7 million in damages. Both parties filed post-trial

motions on October 21, 2021, in which (x) Qiagen seeks to overturn the jury verdict by requesting judgment as a matter of law or, in the alternative, a new trial or altered judgment on the issues of non-infringement, invalidity and damages, and (y) ArcherDX seeks a permanent injunction on infringing products and services approved for clinical diagnosis by a regulatory authority, ongoing royalty for products not enjoined, supplemental damages, interest and enhanced damages.

9. Stockholders' equity

Shares outstanding

Shares of convertible preferred and common stock were as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Convertible preferred stock:			
Shares outstanding, beginning of period	125	125	3,459
Conversion into common stock	(125)	—	(3,334)
Shares outstanding, end of period	—	125	125
Common stock:			
Shares outstanding, beginning of period	185,886	98,796	75,481
Common stock issued in private placement	—	16,320	—
Common stock issued in connection with public offering	8,932	24,005	11,136
Common stock issued on exercise of stock options, net	2,068	2,659	468
Common stock issued pursuant to vesting of RSUs	4,325	5,304	2,683
Common stock issued pursuant to exercises of warrants	208	968	31
Common stock issued pursuant to employee stock purchase plan	654	671	455
Common stock issued pursuant to acquisitions	25,918	37,163	5,208
Common stock issued upon conversion of preferred stock	125	—	3,334
Shares outstanding, end of period	228,116	185,886	98,796

Convertible preferred stock

In August 2017, in a private placement to certain accredited investors, we issued shares of our Series A convertible preferred stock which are convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like. The Series A convertible preferred stock is a non-voting common stock equivalent with a par value of \$0.0001 and has the right to receive dividends first or simultaneously with payment of dividends on common stock. In the event of any liquidation or dissolution of the Company, the Series A preferred stock is entitled to receive \$0.001 per share prior to the payment of any amount to any holders of capital stock ranking junior to the Series A preferred stock and thereafter shall participate pari passu with the holders of our common stock (on an as-if-converted-to-common-stock basis). During the year ended December 31, 2021, 124,913 shares of Series A convertible preferred stock were converted into 124,913 shares of common stock. As of December 31, 2021, there were no shares of Series A convertible preferred stock outstanding.

Sales Agreement

In May 2021, we entered into a sales agreement (the "2021 Sales Agreement") with Cowen and Company, LLC ("Cowen") under which we may offer and sell from time to time at our sole discretion shares of our common stock through Cowen as our sales agent, in an aggregate amount not to exceed \$400.0 million. Per the terms of the agreement, Cowen will receive a commission of up to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2021 Sales Agreement.

In August 2018, we entered into a Common Stock Sales Agreement (the "2018 Sales Agreement") with Cowen under which we may have offered and sold from time to time at our sole discretion shares of our common stock through Cowen as our sales agent, in an aggregate amount not to exceed \$75.0 million. Per the terms of the agreement, Cowen received a commission equal to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2018 Sales Agreement. In March 2019, we amended the 2018 Sales Agreement to increase the aggregate amount of our common stock to be sold under this agreement to an amount not to exceed

\$175.0 million. During 2018, 2019 and 2020, we sold 8.7 million shares of our common stock for gross proceeds of the full \$175.0 million under this agreement, and generated net proceeds of \$169.1 million.

Public offerings

In January 2021, we sold, in an underwritten public offering, an aggregate of 8.9 million shares of our common stock at a price of \$51.50 per share, for gross proceeds of \$460.0 million and net proceeds of approximately \$434.3 million after deducting underwriting discounts and commissions and offering expenses.

In April 2020, we sold, in an underwritten public offering, an aggregate of 20.4 million shares of our common stock at a price of \$9.00 per share, for gross proceeds of \$184.0 million and net proceeds of \$173.0 million after deducting underwriting discounts and commissions and offering expenses.

Private placement

In connection with our acquisition of ArcherDX, in June 2020 we entered into a definitive agreement to sell \$275.0 million in common stock in a private placement at a price of \$16.85 per share. We received net proceeds of \$263.7 million after deducting placement fees and offering expenses upon the closing of the private placement in October 2020, concurrently with our acquisition of ArcherDX.

10. Stock incentive plans

Stock incentive plans

In 2010, we adopted the 2010 Incentive Plan (the "2010 Plan"). The 2010 Plan provides for the granting of stock-based awards to employees, directors and consultants under terms and provisions established by our Board of Directors. Under the terms of the 2010 Plan, options may be granted at an exercise price not less than the fair market value of our common stock. For employees holding more than 10% of the voting rights of all classes of stock, the exercise prices for incentive and nonstatutory stock options must be at least 110% of fair market value of our common stock on the grant date, as determined by our Board of Directors. The terms of options granted under the 2010 Plan may not exceed ten years.

In January 2015, we adopted the 2015 Stock Incentive Plan (the "2015 Plan"), which became effective upon the closing of our initial public offering. Shares outstanding under the 2010 Plan were transferred to the 2015 Plan upon effectiveness of the 2015 Plan. The 2015 Plan provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 through January 1, 2025. In addition, shares subject to awards under the 2010 Plan that are forfeited or terminated will be added to the 2015 Plan. The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock units, stock appreciation rights and other forms of equity compensation, all of which may be granted to employees, including officers, non-employee directors and consultants. Additionally, the 2015 Plan provides for the grant of cash-based awards.

Options granted generally vest over a period of four years. Typically, the vesting schedule for options granted to newly hired employees provides that 1/4 of the award vests upon the first anniversary of the employee's date of hire, with the remainder of the award vesting monthly thereafter at a rate of 1/48 of the total shares subject to the option. All other options typically vest in equal monthly installments over the four-year vesting schedule. Upon the acquisition of ArcherDX in October 2020, any option that was outstanding was converted into a fully vested option to purchase a share of our common stock, which resulted in the issuance of options to purchase 3.7 million shares of our common stock.

RSUs generally vest over a period of three years. Typically, the vesting schedule for RSUs provides that 1/3 of the award vests upon each anniversary of the grant date, with certain awards that include a portion that vests immediately upon grant. We have certain awards granted in connection with our management incentive plan that vest over a period of two years. In June 2019, we granted Time-based RSUs in connection with the acquisition of Singular Bio which vest in three equal installments over a period of 18 months and PRSUs that vest based on the achievement of performance conditions; see further details in Note 4, "Business combinations." In December 2020, we granted RSUs in connection with an asset acquisition which vest in two equal installments in December 2021 and December 2022, subject to the employees' continued service with us.

Under our management incentive compensation plan, in July 2019 we granted PRSUs to our executive officers as well as other specified senior level employees based on the level of achievement of a specified 2019 revenue goal. One-third of the 0.8 million shares that were ultimately awarded under this plan vested during the year ended December 31, 2020 and the remaining shares will vest through March 2022. In June 2020, we granted 0.3 million PRSUs under this plan which are based on the level of achievement of a specified 2020 cash burn goal. Upon achievement of the specified 2020 cash burn goal, 0.3 million shares were ultimately awarded and began vesting in

2021 over a one year period. These PRSUs had a grant date fair value of \$4.2 million based on an estimated issuance of 0.3 million shares and expectation of the performance conditions. During the year ended December 31, 2021, \$2.7 million was recorded as stock-based compensation expense related to the awards.

Activity under the 2010 Plan and the 2015 Plan is set forth below (in thousands, except per share amounts and years):

	Shares Available For Grant	Stock Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Balance at December 31, 2020	7,447	4,877	\$ 7.75	6.8	\$ 166,130
Additional shares reserved	17,138	—			
Options granted	(267)	267	\$ 32.25		
Options cancelled	42	(42)	\$ 25.24		
Options exercised	—	(2,068)	\$ 4.34		
RSUs and PRSUs granted	(15,322)	—			
RSUs and PRSUs cancelled	1,204	—			
Balance at December 31, 2021	<u>10,242</u>	<u>3,034</u>	\$ 11.98	5.5	\$ 16,431
Options exercisable at December 31, 2021		<u>2,598</u>	\$ 9.75	4.9	\$ 15,989
Options vested and expected to vest at December 31, 2021		<u>3,009</u>	\$ 11.93	5.4	\$ 16,401

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of our common stock for stock options that were in-the-money.

The weighted-average fair value of options to purchase common stock granted was \$22.46, \$10.10 and \$14.52 in the years ended December 31, 2021, 2020 and 2019, respectively.

The total grant-date fair value of options to purchase common stock vested was \$2.4 million, \$2.8 million and \$4.3 million in the year ended December 31, 2021, 2020, and 2019, respectively.

The intrinsic value of options to purchase common stock exercised was \$55.0 million, \$104.4 million and \$6.3 million in the years ended December 31, 2021, 2020 and 2019, respectively.

The following table summarizes RSU, including PRSU, activity (in thousands, except per share data):

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance at December 31, 2020	6,602	\$ 12.89
RSUs granted	6,468	\$ 30.01
Time-based RSUs and PRSUs granted - variable	8,645	\$ 31.23
PRSUs granted	209	\$ 34.75
RSUs vested	(4,473)	\$ 22.16
RSUs cancelled	(1,204)	\$ 26.11
Balance at December 31, 2021	<u>16,247</u>	\$ 26.21

2015 ESPP

In January 2015, we adopted the 2015 ESPP, which became effective upon the closing of the IPO. Employees participating in the ESPP may purchase common stock at 85% of the lesser of the fair market value of common stock on the purchase date or last trading day preceding the offering date. At December 31, 2021, cash received from payroll deductions pursuant to the ESPP was \$3.0 million.

The ESPP provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 and continuing through January 1, 2025. At December 31, 2021, a total of 2.1 million shares of common stock are reserved for issuance under the ESPP.

Stock-based compensation

We use the grant date fair value of our common stock to value options when granted. In determining the fair value of stock options and ESPP purchases, we use the Black-Scholes option-pricing model and, for stock options, the assumptions discussed below. Each of these inputs is subjective and its determination generally requires significant judgment. The fair value of RSU and PRSU awards is based on the grant date share price. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and RSUs and on an accelerated basis for PRSUs.

Expected term—The expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method (based on the midpoint between the vesting date and the end of the contractual term).

Expected volatility—We estimate expected volatility based on the historical volatility of our common stock over a period equal to the expected term of stock option grants and RSUs and over the expected six-month term ESPP purchase periods.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Dividend yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

The fair value of share-based payments for stock options granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model based on the following assumptions:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	6.0	6.0	6.0
Expected volatility	73.5%	71.0%	64.2%
Risk-free interest rate	1.1%	0.5%	2.6%

The fair value of shares purchased pursuant to the ESPP is estimated using the Black-Scholes option pricing model. For the years ended December 31, 2021, 2020 and 2019, the weighted-average grant date fair value per share for the ESPP was \$8.10, \$10.98 and \$6.05, respectively.

The fair value of the shares purchased pursuant to the ESPP was estimated using the following assumptions:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	0.5	0.5	0.5
Expected volatility	66.1%	105.7%	66.3%
Risk-free interest rate	0.0%	0.1%	2.0%

The following table summarizes stock-based compensation expense for the years ended December 31, 2021, 2020 and 2019, included in the consolidated statements of operations (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Cost of revenue	\$ 12,033	\$ 8,713	\$ 4,563
Research and development	92,407	91,762	52,450
Selling and marketing	15,641	14,418	7,641
General and administrative	59,994	43,854	11,294
Total stock-based compensation expense	\$ 180,075	\$ 158,747	\$ 75,948

At December 31, 2021, unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was \$5.8 million, which we expect to recognize on a straight-line basis over a weighted-average period of 2.3 years. Unrecognized compensation expense related to RSUs, including PRSUs, and awards that are contingently issuable upon the completion of certain milestones related to our acquisitions of ArcherDX and IntelliGene Health Informatics, LLC at December 31, 2021, net of estimated forfeitures, was \$327.4 million, which we expect to recognize on a straight-line basis over a weighted-average period of 2.0 years.

11. Income taxes

We recorded a benefit for income taxes in the years ended December 31, 2021, 2020 and 2019. The components of net loss before taxes by U.S. and foreign jurisdictions are as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
United States	\$ 414,657	\$ 712,409	\$ 260,531
Foreign	1,206	1,861	(116)
Total	<u>\$ 415,863</u>	<u>\$ 714,270</u>	<u>\$ 260,415</u>

The components of the provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Current:			
Foreign	2,069	171	85
Total current benefit for income taxes	<u>2,069</u>	<u>171</u>	<u>85</u>
Deferred:			
Federal	(28,348)	(94,279)	(16,011)
State	(8,809)	(17,730)	(2,524)
Foreign	(1,769)	(262)	—
Total deferred benefit for income taxes	<u>(38,926)</u>	<u>(112,271)</u>	<u>(18,535)</u>
Total income tax benefit	<u>\$ (36,857)</u>	<u>\$ (112,100)</u>	<u>\$ (18,450)</u>

The following table presents a reconciliation of the tax expense computed at the statutory federal rate and our tax expense for the periods presented:

	Year Ended December 31,		
	2021	2020	2019
U.S. federal taxes at statutory rate	21.0 %	21.0 %	21.0 %
State taxes (net of federal benefit)	7.3 %	3.4 %	3.7 %
Stock-based compensation	(1.2)%	(1.6)%	1.3 %
Research and development credits	3.8 %	1.1 %	— %
Non-deductible expenses	(0.9)%	(0.7)%	(1.6)%
Foreign tax differential	(0.1)%	— %	— %
Acquisition contingent liabilities	18.5 %	(0.8)%	— %
Change in valuation allowance	(39.5)%	(6.7)%	(17.3)%
Total	<u>8.9 %</u>	<u>15.7 %</u>	<u>7.1 %</u>

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	As of December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 530,663	\$ 337,866
Tax credits	36,188	19,969
Revenue recognition differences	2,560	9,099
Leasing liabilities	34,403	14,274
Accruals and other	36,689	37,677
Gross deferred tax assets	640,503	418,885
Valuation allowance	(386,950)	(209,308)
Total deferred tax assets	253,553	209,577
Deferred tax liabilities:		
Amortization and depreciation	(271,517)	(233,150)
Convertible Senior Notes	—	(14,658)
Leasing Assets	(33,732)	(13,307)
Total deferred tax liabilities	(305,249)	(261,115)
Net deferred tax liabilities	\$ (51,696)	\$ (51,538)

In December 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law making significant changes to the Internal Revenue Code. Changes included among other items, a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%. Although the Tax Act was generally effective January 1, 2018, GAAP required recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017. As a result of the lower corporate tax rate enacted as part of the Tax Act, during 2017, the Company recorded a provisional estimate to reduce deferred tax assets by \$48.8 million offset by a corresponding reduction in the valuation allowance resulting in no net impact to our income tax benefit or expense.

In December 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, during 2017, we recorded a provisional estimate which resulted in a \$48.8 million reduction in deferred tax assets and in the fourth quarter of 2018, we completed our analysis of the impact of the Tax Act and determined that no material adjustments were required to the provisional amounts previously recorded.

The Company historically established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets. In 2021 the Company released approximately \$37.2 million of its valuation allowance to account for acquired intangibles that support the future realization of some of the Company's deferred tax assets. Due to the overall increase of deferred tax assets, the Company's valuation allowance also increased from the prior year. The Company's valuation allowance increased by \$177.6 million, \$64.0 million, and \$23.4 million during the years ended December 31, 2021, 2020, and 2019, respectively.

As of December 31, 2021, the Company had net operating loss carryforwards of approximately \$2.2 billion and \$1.3 billion available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. Of the \$2.2 billion, \$284.9 million will begin to expire in 2030 while \$1.9 billion have no expiration date. The state net operating loss carryforwards will begin to expire in 2030.

As of December 31, 2021, the Company had research and development credit carryforwards of approximately \$58.3 million and \$25.2 million available to reduce our future tax liability, if any, for federal and state income tax purposes, respectively. The federal credit carryforwards begin to expire in 2030. California credit carryforwards have no expiration date.

Internal Revenue Code ("IRC") section 382 places a limitation (the "Section 382 limitation" or "annual limitation") on the amount of taxable income that can be offset by net operating loss carryforwards after a change in control (generally greater than 50% change in ownership) of a loss corporation. Similar provisions exist for states. In addition, and as a result of the acquisitions of Good Start Genetics and CombiMatrix in 2017, acquisitions of Singular Bio, Jungla, and Clear Genetics in 2019, acquisitions of YouScript and ArcherDX in 2020, and acquisitions of One

Codex, Genosity, Ciitizen, and Stratify in 2021, tax loss carryforwards from acquired entities are also subject to the Section 382 limitation due to the change in control in the acquired entities in the current year.

In addition, as a result of equity issued in connection with various acquisitions, the Company also performed a section 382 analysis in 2021 with respect to our operating loss and credit carryforwards. The Company concluded while an ownership change occurred in 2020 as defined under IRC section 382, none of the Company's net operating loss carryforwards would expire unused solely as a result of annual limitations imposed on the use of the carryforwards under IRC sections 382 and 383.

Our policy with respect to undistributed foreign subsidiaries' earnings is to consider those earnings to be indefinitely reinvested. As a result of the enactment in the Tax Cuts and Job Acts of 2017, if and when funds are actually distributed in the form of dividends or otherwise, we expect minimal tax consequences, except for withholding taxes, which would be applicable in some jurisdiction.

As of December 31, 2021, we had unrecognized tax benefits of \$46.7 million, which primarily relates to research and development credits, \$1.9 million of which would currently affect the Company's effective tax rate if recognized due to the Company's valuation allowance against its deferred tax assets. During the year, the Company benchmarked the reserves of similar tax positions within the industry based on IRS and state audits of comparable companies. Based on its analysis, the Company decreased its unrecognized tax benefits to more closely align with other comparable companies within the industry. As these reserves relate primarily to research and development credits which have a full valuation allowance, such adjustments did not impact the Company's income tax provision. Unrecognized tax benefits are not expected to materially change in the next 12 months.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year ended December 31,		
	2021	2020	2019
Unrecognized tax benefits, beginning of period	\$ 21,965	\$ 26,985	\$ 16,375
Gross increases—current period tax positions	18,165	8,368	10,311
Gross increases—prior period tax positions	6,539	53	299
Gross decreases—prior period tax positions	—	(13,441)	—
Unrecognized tax benefits, end of period	\$ 46,669	\$ 21,965	\$ 26,985

The Company's policy is to include penalties and interest expense related to income taxes as a component of tax expense. The Company has not accrued interest and penalties related to the unrecognized tax benefits reflected in the financial statements for the years ended December 31, 2021, 2020 and 2019.

The Company's major tax jurisdictions are the United States and California. All of the Company's tax years will remain open for examination by the Federal and state tax authorities for three and four years, respectively, from the date of utilization of the net operating loss or research and development credit. The Company does not have any tax audits pending.

12. Net loss per share

The following table presents the calculation of basic and diluted net loss per share (in thousands, except per share data):

	Year ended December 31,		
	2021	2020	2019
Net loss	\$ (379,006)	\$ (602,170)	\$ (241,965)
Shares used in computing net loss per share, basic and diluted	210,946	134,587	90,859
Net loss per share, basic and diluted	\$ (1.80)	\$ (4.47)	\$ (2.66)

The following common stock equivalents have been excluded from diluted net loss per share because their inclusion would be anti-dilutive (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Shares of common stock subject to outstanding options	4,069	6,878	3,662
Shares of common stock subject to outstanding warrants	29	405	592
Shares of common stock subject to outstanding RSUs	9,146	5,590	5,293
Shares of common stock subject to outstanding PRSUs	737	1,658	1,860
Shares of common stock pursuant to ESPP	425	294	239
Shares of common stock underlying Series A convertible preferred stock	93	125	702
Shares of common stock subject to Convertible Senior Notes conversion	38,403	8,371	3,612
Total shares of common stock equivalents	52,902	23,321	15,960

13. Geographic information

Revenue by country is determined based on the billing address of the customer and is summarized as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
United States	\$ 404,013	\$ 255,680	\$ 202,550
Canada	7,553	4,529	4,356
Rest of world	48,883	19,389	9,918
Total revenue	\$ 460,449	\$ 279,598	\$ 216,824

As of December 31, 2021, 2020 and 2019, our long-lived assets were primarily located in the United States other than operating lease assets representing our right-of-use for leased facilities in Australia, Belgium and Israel.

14. Selected quarterly data (unaudited)

The following table summarizes our quarterly financial information for 2021 and 2020 (in thousands, except per share amounts):

	Three Months Ended			
	March 31, 2021	June 30, 2021	September 30, 2021	December 31, 2021
Revenue	\$ 103,621	\$ 116,312	\$ 114,395	\$ 126,121
Cost of revenue	\$ 75,491	\$ 89,331	\$ 87,741	\$ 96,106
(Loss) income from operations	\$ (112,364)	\$ 128,609	\$ (193,312)	\$ (214,574)
Net (loss) income	\$ (109,492)	\$ 133,786	\$ (198,176)	\$ (205,124)
Net loss per share, basic ⁽¹⁾	\$ (0.56)	\$ 0.66	\$ (0.91)	\$ (0.90)
Net loss per share, diluted ⁽¹⁾	\$ (0.56)	\$ 0.53	\$ (0.91)	\$ (0.90)

	Three Months Ended			
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
Revenue	\$ 64,248	\$ 46,191	\$ 68,728	\$ 100,431
Cost of revenue	\$ 40,422	\$ 42,952	\$ 46,643	\$ 68,258
Loss from operations	\$ (97,784)	\$ (142,082)	\$ (80,823)	\$ (331,483)
Net loss	\$ (98,527)	\$ (166,403)	\$ (102,902)	\$ (234,338)
Net loss per share, basic and diluted ⁽¹⁾	\$ (0.99)	\$ (1.29)	\$ (0.78)	\$ (1.30)

⁽¹⁾ Net loss (income) per share is computed independently for each of the quarters presented. Therefore, the sum of quarterly net loss per share information may not equal annual net loss per share.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

ITEM 9A. Controls and Procedures

Evaluation of disclosure controls and procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer) have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation described in Item 9A above that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management’s annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining internal control over our financial reporting. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework (2013 Framework). Based on the assessment using those criteria, our management concluded that, as of December 31, 2021, our internal control over financial reporting was effective. Our independent registered public accounting firm, Ernst & Young LLP, has issued an audit report with respect to our internal control over financial reporting, which appears in Part II, Item 8. of this Annual Report on Form 10-K.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Invitae Corporation

Opinion on Internal Control Over Financial Reporting

We have audited Invitae Corporation's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Invitae Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Invitae Corporation as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements") and our report dated March 1, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP
Redwood City, California
March 1, 2022

ITEM 9B. Other Information

None.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

The information required by this item with respect to directors is incorporated by reference from the information under the caption "Election of Directors," contained in our proxy statement to be filed with the Securities and Exchange Commission no later than 120 days from the end of our fiscal year ended December 31, 2021 in connection with the solicitation of proxies for our 2022 Annual Meeting of Stockholders, or the Proxy Statement. Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption "Information about our executive officers" and is incorporated herein by reference.

There have been no material changes to the procedures by which stockholders may recommend nominees to our Board of Directors.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. To the extent disclosure for delinquent reports is being made, it can be found under the caption "Delinquent Section 16(a) Reports" in the Proxy Statement and is incorporated herein by reference.

Our board of directors has adopted a Code of Business Conduct and Ethics that applies to each of our directors, officers and employees. The Code of Business Conduct and Ethics set forth the basic principles that guide the business conduct of our employees. Our board of directors has also adopted a Code of Ethics for Senior Financial Officers applicable to our Chief Executive Officer and Chief Financial Officer as well as other key management employees addressing ethical issues. The Code of Business Conduct and Ethics and the Code of Ethics for Senior Financial Officers are each posted on our website www.invitae.com. The Code of Business Conduct and Ethics and the Code of Ethics for Senior Financial Officers can only be amended by the approval of a majority of our board of directors. Any waiver to the Code of Business Conduct and Ethics for an executive officer or director or any waiver of the Code of Ethics for Senior Financial Officers may only be granted by our board of directors or our nominating and corporate governance committee and must be timely disclosed as required by applicable law. We have implemented whistleblower procedures that establish formal protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures will be communicated promptly to our audit committee. Stockholders may request a free copy of our Code of Business Conduct and Ethics and Code of Ethics for Senior Financial Officers by contacting Invitae Corporation, Attention: Chief Financial Officer, 1400 16th Street, San Francisco, California 94103. None of the materials on, or accessible through, our website is part of this report or incorporated by reference herein.

To date, there have been no waivers under our Code of Business Conduct and Ethics or Code of Ethics for Senior Financial Officers. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics or Code of Ethics for Senior Financial Officers or waivers of such codes granted to executive officers and directors on our website at <http://www.invitae.com> within four business days following the date of such amendment or waiver.

Our Board of Directors has appointed an Audit Committee, comprised of Christine M. Gorjanc, Geoffrey S. Crouse and Kimber D. Lockhart. The Board of Directors has determined that each of Ms. Gorjanc and Mr. Crouse qualifies as an "audit committee financial expert" under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an "independent director" under the current rules of the New York Stock Exchange and Securities and Exchange Commission rules and regulations.

ITEM 11. Executive Compensation

The information required by this item is incorporated by reference from the information under the captions "Election of Directors—Director Compensation," "Election of Directors—Compensation Committee Interlocks and Insider Participation" and "Executive Compensation" contained in the Proxy Statement.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference to the disclosure appearing under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation—Equity Compensation Plan Information" contained in the Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference from the information under the captions "Certain Relationships and Related Transactions," "Corporate Governance" and "Director Independence" contained in the Proxy Statement.

ITEM 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference from the information under the caption "Ratification of the Appointment of Independent Registered Public Accounting Firm" contained in the Proxy Statement.

PART IV

ITEM 15. Exhibit and Financial Statement Schedules

- (a) Documents filed as part of this report
1. *Financial Statements*: Reference is made to the Index to Financial Statements of Invitae Corporation included in Item 8. of Part II hereof.
 2. *Financial Statement Schedules*: All schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto.
 3. *Exhibits*: See Item 15(b) below. Each management contract or compensating plan or arrangement required to be filed has been identified.

(b) Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
2.1 [@]	Agreement and Plan of Merger and Plan of Reorganization, dated as of June 21, 2020, by and among Invitae Corporation, Apollo Merger Sub A Inc., Apollo Merger Sub B LLC, ArcherDX, Inc. and Kyle Lefkoff, solely in his capacity as holders' representative.	8-K	2.1	6/24/2020	
2.2 [@]	Stock Purchase and Merger Agreement, dated as of July 11, 2019, by and among Invitae Corporation, Jumanji, LLC, Jungla Inc., and Fortis Advisors LLC.	10-Q	2.2	8/6/2019	
2.3 ^{@^}	Agreement and Plan of Merger, dated as of November 8, 2019, by and among Invitae Corporation, Catalina Merger Sub A Inc., Catalina Merger Sub B LLC, Clear Genetics, Inc. and Shareholder Representative Services LLC.	10-K	2.3	3/2/2020	
2.4 ^{@^}	Share Purchase Agreement, dated as of March 10, 2020, by and among Invitae Corporation, Invitae Netherlands, B.V. and Peter Schols.	10-Q	2.1	5/11/2020	
2.5 ^{@^}	Agreement and Plan of Merger, dated as of March 10, 2020, by and among Invitae Corporation, Yasawa Merger Sub A Inc., Yasawa Merger Sub B LLC, YouScript Incorporated, and Fortis Advisors LLC, as representative of YouScript Incorporated's stockholders.	10-Q	2.1	8/4/2020	
2.6 ^{@^}	Unit Purchase Agreement, dated as of March 10, 2020, by and among Invitae Corporation, David Colaizzi, Chris Howlett, Anthony Muhlenkamp, Gerald Schneider, and Matt Lehrian.	10-Q	2.2	8/4/2020	
3.1	Restated Certificate of Incorporation.	8-K	3.1	2/23/2015	
3.1.1	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Invitae Corporation.	8-K	3.1	8/1/2017	
3.2	Amended and Restated Bylaws.	8-K	3.2	2/23/2015	
4.1	Form of Common Stock Certificate.	10-K	4.1	2/26/2021	
4.2	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	4.2	3/2/2020	
4.3	Indenture dated as of September 10, 2019, between Invitae Corporation and U.S. Bank National Association, as trustee (including form of Note).	8-K	4.1	9/11/2019	
4.4	Indenture, dated as of April 8, 2021, between Invitae Corporation and U.S. Bank National Association (including form of Note).	8-K	4.1	4/8/2021	
4.5	Amended and Restated Registration Rights Agreement, dated as of July 31, 2017.	8-K	10.4	8/1/2017	
4.6	Registration Rights Agreement, dated as of October 2, 2020, by and among Invitae Corporation and the investors party thereto.	8-K	10.2	10/5/2020	
4.7	Registrations Rights Agreement, dated as of February 8, 2021, by and among the Invitae Corporation and certain securityholders of Reference Genomics, Inc. d/b/a One Codex.				X

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
4.8	Registration Rights Agreement, dated as of September 13, 2021, by and among Invitae Corporation and certain stockholders of Ciitizen Corporation.				X
10.1	Form of Indemnification Agreement between Invitae Corporation and its officers and directors.	S-1 (File No. 333-201433)	10.1	1/9/2015	
10.2	Lease Agreement dated as of September 2, 2015 by and between Invitae Corporation and 1400 16th Street LLC.	8-K	10.1	9/4/2015	
10.3	Lease Agreement, dated as of April 20, 2021, by and between Invitae Corporation and APB Owned LLC.	8-K	10.1	4/23/2021	
10.4 [@]	Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent.	8-K	10.3	10/5/2020	
10.5	Amendment No. 1, dated as of April 3, 2021, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent, to Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent.	8-K	10.2	4/5/2021	
10.6	Amendment No. 2, dated as of September 20, 2021, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent, to Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent.	10-Q	10.1	11/9/2021	
10.7 [#]	Invitae Corporation 2015 Stock Incentive Plan, as amended and restated as of August 31, 2021.	10-Q	10.3	11/9/2021	
10.8 [#]	Form of Notice of Stock Option Grant and Non-Qualified Stock Option Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.	S-1 (File No. 333-201433)	10.6	2/11/2015	
10.9 [#]	Form of Notice of Restricted Stock Award and Restricted Stock Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.	S-1 (File No. 333-201433)	10.7	2/11/2015	
10.10 [#]	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.	8-K	10.1	8/6/2015	
10.11 [#]	Form of Notice of Time-Based Restricted Stock Unit Award and Time-Based Restricted Stock Unit Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan (Inducement).	10-Q	10.2	8/6/2019	
10.12 [#]	Form of Notice of Performance-Based Restricted Stock Unit Award and Performance-Based Restricted Stock Unit Agreement for awards under the Invitae Corporation 2015 Stock Incentive Plan (Inducement).	10-Q	10.3	8/6/2019	
10.13 [#]	Form of Global Restricted Stock Unit Agreement under the Invitae Corporation 2015 Stock Incentive Plan.	10-Q	10.4	11/9/2021	
10.14 [#]	Invitae Corporation Employee Stock Purchase Plan, as amended and restated as of October 14, 2021.	10-Q	10.2	11/9/2021	
10.15 [#]	ArcherDX, Inc. 2015 Equity Incentive Plan, as amended, and forms of agreements thereunder.	10-K	10.21	2/26/2021	
10.16 [#]	Stratify Genomics Inc. 2018 Equity Incentive Plan, as amended by Amendment No. 1 and Amendment No. 2.				X

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
10.17	Form of Warrant to Purchase Common Stock between Oxford Capital, LLC and Invitae Corporation.	10-K	10.14	3/16/2017	
10.18	Sales Agreement, dated May 4, 2021, between Invitae Corporation and Cowen and Company, LLC.	8-K	1.1	5/4/2021	
10.19#	Offer Letter, dated as of June 1, 2020, by and between Invitae Corporation and Kenneth D. Knight.	8-K	10.1	6/26/2020	
10.20#	Offer Letter, dated May 19, 2021, between Invitae Corporation and Roxi Wen.	8-K	10.1	6/11/2021	
10.21#	Change in Control and Severance Agreement, between Invitae Corporation and Sean George.	10-Q	10.5	8/9/2021	
10.22#	Form of Change in Control and Severance Agreement, between Invitae Corporation and certain officers.	10-Q	10.6	8/9/2021	
10.23	Securities Purchase Agreement, dated as of June 21, 2020, by and among Invitae Corporation and the investors identified therein.	8-K	10.1	6/24/2020	
10.24	Support Agreement, dated as of September 23, 2020, by and among Invitae Corporation and certain securityholders of ArcherDX, Inc.	8-K	10.4	10/5/2020	
10.25	Investment Agreement, dated as of April 3, 2021, by and among Invitae Corporation and parties listed therein (including form of Indenture relating to 1.50% Convertible Senior Notes due 2028).	8-K	10.1	4/5/2021	
21.1	List of Subsidiaries.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (contained on the signature page to this Form 10-K).				X
31.1	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Principal Financial and Accounting Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).				X
32.2	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).				X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase				X
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document and included as Exhibit 101).				

Indicates management contract or compensatory plan or arrangement.

@ The schedules and exhibits to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

^ Portions of this exhibit have been redacted in accordance with Item 601(b)(2)(ii) and Item 601(b)(10)(iv) of Regulation S-K.

Copies of the above exhibits not contained herein are available to any stockholder, upon payment of a reasonable per page fee, upon written request to: Chief Financial Officer, Invitae Corporation, 1400 16th Street, San Francisco, California 94103.

(c) Financial Statement Schedules: Reference is made to Item 15(a) 2 above.

ITEM 16. Form 10-K Summary

Not applicable.

EXHIBIT 3

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

[] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File No. 001-36847

Invitae Corporation

(Exact name of the registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

27-1701898
(I.R.S. Employer Identification No.)

1400 16th Street, San Francisco, California 94103

(Address of principal executive offices, Zip Code)

(415) 374-7782

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Table with 3 columns: Title of each class, Trading Symbol, Name of exchange on which registered. Row 1: Common Stock, \$0.0001 par value per share, NVTA, New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [X] No []

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [] No [X]

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No []

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No []

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [X] Accelerated filer [] Non-accelerated filer [] Smaller reporting company [] Emerging growth company []

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. []

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. [X]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of June 30, 2020, the aggregate market value of common stock held by non-affiliates of the Registrant was approximately \$4.0 billion, based on the closing price of the common stock as reported on The New York Stock Exchange for that date.

The number of shares of the registrant's Common Stock outstanding as of February 19, 2021 was 196,654,925.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III incorporate by reference information from the registrant's proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant's 2021 Annual Meeting of Stockholders.

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SIGNATURES

Forward-Looking Statements.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this report other than statements of historical fact, including statements identified by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect” and similar expressions, are forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our views regarding the future of genetic testing and its role in mainstream medical practice;
- the impact of COVID-19 on our business and the actions we may take in response thereto;
- our mission and strategy for our business, products and technology, including our ability to expand our content and develop new content while maintaining attractive pricing, further enhance our genetic testing service and the related user experience, build interest in and demand for our tests and attract potential partners;
- the implementation of our business model;
- the expected benefits from and our ability to integrate our acquisitions;
- the rate and degree of market acceptance of our tests and genetic testing generally;
- our ability to scale our infrastructure and operations in a cost-effective manner;
- the timing of and our ability to introduce improvements to our genetic testing platform and to expand our assays to include additional genes;
- the timing and results of studies with respect to our tests;
- developments and projections relating to our competitors and our industry;
- our competitive strengths;
- the degree to which individuals will share genetic information generally, as well as share any related potential economic opportunities with us;
- our commercial plans, including our sales and marketing expectations as well as our ability to expand internationally;
- our ability to obtain and maintain adequate reimbursement for our tests;
- regulatory developments in the United States and foreign countries;
- our ability to attract and retain key scientific or management personnel;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- our ability to obtain funding for our operations and the growth of our business, including potential acquisitions;
- our financial performance;
- the impact of accounting pronouncements and our critical accounting policies, judgments, estimates and assumptions on our financial results;
- our expectations regarding our future revenue, cost of revenue, operating expenses and capital expenditures, and our future capital requirements; and
- the impact of tax laws on our business.

Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Item 1A of this report. Although we believe that the expectations and assumptions reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statements in this report speak only as of the date of this report. We expressly disclaim any obligation or undertaking to update any forward-looking statements.

This report contains statistical data and estimates that we obtained from industry publications and reports. These publications typically indicate that they have obtained their information from sources they believe to be reliable, but do not guarantee the accuracy and completeness of their information. Some data contained in this report is also based on our internal estimates. Although we have not independently verified the third-party data, we believe it to be reasonable.

In this report, all references to “Invitae,” “we,” “us,” “our,” or “the Company” mean Invitae Corporation.

Invitae and the Invitae logo are trademarks of Invitae Corporation. We also refer to trademarks of other companies and organizations in this report.

Summary of Risk Factors.

Our business is subject to numerous risks and uncertainties that could affect our ability to successfully implement our business strategy and affect our financial results. You should carefully consider all of the information in this report and, in particular, the following principal risks and all of the other specific factors described in Item 1A. of this report, "Risk Factors," before deciding whether to invest in our company.

- We face risks related to health epidemics, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.
- We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.
- Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.
- We have acquired and may continue to acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.
- If third-party payers, including managed care organizations, private health insurers and government health plans do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.
- We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the market. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.
- We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.
- Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation, including ongoing litigation with respect to alleged intellectual property infringement against ArcherDX, Inc., or ArcherDX, will require us to spend significant time and money, could, in the future, prevent us from selling certain of our tests, and could have a material adverse effect on our business, financial condition and stock price.
- We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.
- We need to scale our infrastructure in advance of demand for our tests, and our failure to generate sufficient demand for our tests would have a negative impact on our business and our ability to attain profitability.
- If we are not able to continue to generate substantial demand of our tests, our commercial success will be negatively affected.
- If ArcherDX's products and services do not perform as expected, we may not realize the expected benefits of our recent acquisition of ArcherDX.
- The future growth of our distributed products business is partially dependent upon regulatory approval and market acceptance of our in vitro diagnostic, or IVD products, including STRATAFIDE and Personalized Cancer Monitoring, or PCM.
- Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.

PART I

ITEM 1. Business

Overview

Invitae is in the business of delivering genetic testing services that support a lifetime of patient care – from inherited disease diagnoses, to family planning, to proactive health screening to personalized diagnosis, treatment and monitoring of cancer. Those tests are delivered via a unique, rapidly expanding platform that serves patients, healthcare providers, biopharma companies and other partners, thereby capturing the broad potential of genetics and helping to expand its use across the healthcare continuum. Invitae applies proprietary design, process automation, robotics and bioinformatics software solutions to achieve efficiencies in sample processing and complex variant interpretation, allowing medical interpretation at scale. The result is a new and simplified process for obtaining and using affordable, high-quality genetic information to inform critical healthcare decisions. That access and scale also enable genomic information to speed the discovery and development of new personalized medical therapies — all while making clinical genetic testing available to billions of people.

By pioneering new ways of sharing, understanding and applying genetic information, Invitae is transforming the field of genetics from a series of one-time, one-dimensional queries to a lifelong clinical dialogue with our genes using complex analyses and information management to improve medical decisions and optimize health interventions.

Mission and strategy

Invitae's mission is to bring comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people. Our goal is to aggregate a majority of the world's genetic information into a comprehensive network that enables sharing of data among network participants to improve healthcare and clinical outcomes.

We were founded on four core principles:

- Patients should own and control their own genetic information;
- Healthcare professionals are fundamental in ordering and interpreting genetic information;
- Driving down the price of genetic information will increase its clinical and personal utility; and
- Genetic information is more valuable when shared.

Our strategy for long-term growth centers on five key drivers of our business, which we believe work in conjunction to create a flywheel effect extending our leadership position in the new market we are building:



- **Expanding our content offering.** We intend to continue steadily adding additional testing and analysis content to the Invitae platform, ultimately leading to affordable and ongoing access to the molecular information that enables personalized medicine. The breadth and depth of our offering is a core and central contribution to an improved user experience.

- **Creating a unique user experience.** A state-of-the-art interactive platform will enhance our service offering, leverage the uniquely empowering characteristics of online sharing of genetic information and, we believe, enable a superior economic offering to clients. We intend to continue to expend substantial efforts developing, acquiring and implementing technology-driven improvements to our customers' experience. We believe that an enhanced user experience and the resulting benefits to our brand and reputation will help draw customers to us over and above our direct efforts to do so.
- **Driving volume.** We intend to increase our brand equity and visibility through a commitment to precision testing results, excellent service and a variety of marketing and promotional techniques, including scientific publications and presentations, sales, marketing, public relations, social media and web technology vehicles. We believe that rapidly increasing the number of customers using our platform helps us to attract partners.
- **Attracting partners.** As we add more customers to our platform, we believe our business becomes particularly attractive to potential partners that can help the patients in our network further benefit from their genetic information or that provide us access to new customers who may wish to join our network. We believe the cumulative effect of the increased volume brought by these strategic components will allow us to lower the cost of our service and expand patient access globally.
- **Lowering the cost and price of genetic information.** Our goal is to provide customers with a broad menu of genetic content at a reasonable price and rapid turn-around times in order to grow volume and, in turn, achieve greater economies of scale. As our customers and our business benefit from further cost savings, we expect that those cost savings will allow us to deliver still more comprehensive information at decreasing prices and further improve the customer experience, allowing us to reap the cumulative benefits from all of the efforts outlined above.

We seek to differentiate our service in the market by establishing an exceptional experience for our customers. To that end, we believe that elevating the needs of the customer over those of our other stakeholders is essential to our success. Thus, in our decision-making processes, we strive to prioritize, in order:

- The needs of our customers;
- Motivating our employees to serve our customers; and
- Our long-term stockholder value.

We are certain that focusing on customers as our top priority rather than short-term financial goals is the best way to build and operate an organization for maximum long-term value creation.

Business overview

We are focused on making comprehensive, high-quality genetic information more accessible by lowering the cost of genetic testing, by utilizing a testing delivery platform that is accessible to patients throughout their lives, by enabling a growing network of partners to increase the utility of genetic information across the healthcare continuum, and, ultimately, by managing that information on behalf of our customers, enabling improved health and the advancement of molecular medicine around the globe.

As our market share grows, we expect that our business will grow in three stages:

- 1) **Genetic testing:** making genetic testing more affordable and more accessible with fast turnaround time. We believe that there is a significant market opportunity for high-volume, low-cost genetic testing that allows us to serve a large number of customers. We launched our first commercial offering in November 2013 with an offering of approximately 200 genes, growing the test menu over time to include more than 20,000 genes to help diagnose disease, inform family planning, and serve healthy individuals. In 2020, we processed billable volume of approximately 659,000 units and generated revenue of \$279.6 million reflecting an approximate 41% and 29% increase over 2019 billable volume and revenue, respectively.

- 2) **Genome network:** sharing genetic information on a global scale to advance science and medicine. We are focusing our efforts on partnering with patients, family members, healthcare professionals, payers, industry professionals, researchers, and clinical trial sponsors to advance the development of our genome network. Our goal is to enable and build a network through which individuals and organizations can access, aggregate, and customize genetic information in order to participate in research, clinical trials, treatment planning, or other related purposes that may benefit the individual and/or their clinician. Individuals can also share information if they feel it will benefit them or will contribute more broadly to furthering knowledge about their conditions.

In addition to investing in informatics solutions and infrastructure to support network development, we have been expanding our partnerships, which now number more than 100 of the world's leading biopharmaceutical companies supporting improved patient diagnosis, clinical trial recruitment and other research-related initiatives. Our biopharmaceutical industry partnerships are complemented by partnerships with leading health systems, executive health programs and leading research institutions, including The Christ Hospital Health Network, the Cleveland Clinic, the Geisinger Health System, the Mayo Clinic, Memorial Sloan Kettering Cancer Center, MedCan, and Stanford Health Care, among others.

Through our recent acquisition of ArcherDX, we partner with global biopharmaceutical companies such as AstraZeneca AB (Publ), Illumina and Merck KGaA, Darmstadt, Germany through collaboration agreements to bring new treatment options for patients to market faster by enabling clinical research and trials.

- 3) **Genome management:** building a secure and trusted genome management infrastructure. By generating and storing large amounts of individualized genetic information for every patient sample and enabling the analysis of that cumulative data for broad health research applications, we believe we can create value for all the constituents of our testing platform and partner network. Broad access to centralized, standardized genomic data can benefit patients and their families with information that will improve therapy and outcomes, while it is also expected to aid in the compression of drug development timelines and the greater application of fact-based healthcare decisions throughout life.

Competition

Our competitors include companies that offer molecular genetic testing and consulting services, including specialty and reference laboratories that offer traditional single- and multi-gene tests and biopharmaceutical companies. Principal competitors include companies such as Ambry Genetics, a subsidiary of Konica Minolta Inc.; Athena Diagnostics and Blueprint Genetics, subsidiaries of Quest Diagnostics Incorporated; Baylor-Miraca Genetics Laboratories; Caris Life Sciences, Inc.; Centogene AG; Color Genomics, Inc.; Connective Tissue Gene Test LLC, a subsidiary of Health Network Laboratories, L.P.; Cooper Surgical, Inc.; Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Foundation Medicine, a subsidiary of Roche Holding AG; Fulgent Genetics, Inc.; GeneDx, a subsidiary of OPKO Health, Inc.; Guardant Health, Inc.; Integrated Genetics, Sequenom Inc., Correlagen Diagnostics, Inc., and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings; Myriad Genetics, Inc.; Natera, Inc.; Perkin Elmer, Inc.; PreventionGenetics, LLC; Progenity, Inc.; and Sema4 Genomics; as well as other commercial and academic labs.

In addition, there are a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness, including Illumina, Inc. which is also one of our suppliers. In addition to the companies that currently offer traditional genetic testing services and research centers, other established and emerging healthcare, information technology and service companies may commercialize competitive products including informatics, analysis, integrated genetic tools and services for health and wellness.

We believe the principal competitive factors in our market are:

- breadth and depth of content;
- quality;
- reliability;
- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;
- convenience of testing;
- brand recognition of test provider;
- additional value-added services and informatics tools;
- client service; and
- quality of website content.

We believe that we compare favorably with our competitors on the basis of these factors. However, certain competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, substantially greater financial, technological and research and development resources and selling and marketing capabilities, and more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests, or sell their tests at prices designed to win significant levels of market share. We may not be able to compete effectively against these organizations.

Regulation

Reimbursement

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA (as amended by the Further Consolidated Appropriations Act, 2020 and the Coronavirus Aid, Relief, and Economic Security (CARES) Act) and its implementing regulations, laboratories that realize at least \$12,500 in Medicare Clinical Laboratory Fee Schedule, or CLFS, revenues during the six month reporting period and that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule must report, beginning in 2017, and then in 2022 and every three years thereafter (or annually for “advanced diagnostic laboratory tests”), private payer payment rates and volumes for their tests. We do not believe that our tests meet the current definition of advanced diagnostic laboratory tests, and therefore believe we are required to report private payer rates for our tests on an every three years basis starting next in 2022. CMS uses the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil money penalties.

As set forth under the regulations implementing PAMA, for tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are paid based upon these reported private payer rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the cross-walk or gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test.

The payment rates calculated under PAMA went into effect starting January 1, 2018. Where applicable, reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020. Rates will be held at 2020 levels during 2021, and then, where applicable based upon median private payer rates reported in 2017 or 2022, reduced by up to 15% per test per year in each of 2022 through 2024 (with a second round of private payer rate reporting in 2022 to establish rates for 2023 through 2025).

PAMA codified Medicare coverage rules for laboratory tests by requiring any local coverage determination to be made following the local coverage determination process. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory-specific MACs. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate. It is unclear whether CMS will proceed with contractor consolidation under this authorization.

PAMA also authorized the adoption of new, temporary billing codes and/or unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The American Medical Association has created a new section of billing codes, Proprietary Laboratory Analyses (PLA), to facilitate implementation of this section of PAMA. These codes may apply to one or more of our tests if we apply for PLA coding.

In March 2018, CMS published a national coverage determination, or NCD, for next generation sequencing, or NGS tests for somatic (acquired) cancer testing. CMS subsequently updated this NCD in January 2020 to address coverage for NGS tests for germline (inherited) cancer testing and to clarify certain aspects of Medicare's coverage of NGS for somatic cancer testing. For somatic cancer testing, the updated NCD establishes full coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays that report results using report templates that specify treatment options when offered for their FDA-approved or FDA-cleared use(s), ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer) who have not have previously been tested with the same test using NGS for the same cancer genetic content, and have decided to seek further cancer treatment (e.g., therapeutic chemotherapy.) The NCD also gives MACs the authority to establish local coverage for NGS-based somatic cancer assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It appears that NGS-based somatic cancer tests provided for patients with cancer that do not meet the above-referenced criteria - e.g., patients with earlier stage cancers - are currently nationally non-covered under the NCD.

Effective January 27, 2020, the NCD also establishes full coverage for FDA-approved or FDA-cleared NGS-based germline tests that report results using report templates that specify treatment options when ordered by the patient's treating physician for patients with ovarian or breast cancer, a clinical indication for germline testing for hereditary breast or ovarian cancer, and a risk factor for germline breast or ovarian cancer, provided the patient has not previously been tested with the same germline test using NGS for the same germline genetic content. The NCD also gives MACs the authority to establish local coverage for NGS-based germline tests for ovarian or breast cancer that are not FDA-approved or FDA-cleared, as well as for NGS-based tests for any other cancer diagnosis (regardless of the test's FDA regulatory status) when offered to patients meeting the above-referenced criteria for germline testing. Since we already have local coverage for our germline tests for ovarian and breast cancer, we believe that the NCD will not have a material impact on which of our tests will be reimbursable by CMS for Medicare patients.

Clinical Laboratory Improvement Amendments of 1988, or CLIA

Our clinical reference laboratories in California and Colorado are required to hold certain federal certificates to conduct our business. Under CLIA, we are required to hold certificates applicable to the type of laboratory examinations we perform and to comply with standards covering personnel, facilities administration, inspections, quality control, quality assurance and proficiency testing.

We have current certifications under CLIA to perform testing at our laboratory locations in San Francisco and Irvine, California and Golden, Colorado. To renew our CLIA certifications, we are subject to survey and inspection every two years to assess compliance with program standards. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

If our clinical reference laboratories are out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificates, as well as directed plan of correction, state on-site monitoring, significant civil money penalties, civil injunctive suit or criminal penalties. We must maintain CLIA compliance and certifications to be eligible to bill for diagnostic services provided to Medicare and Medicaid beneficiaries. If we were to be found out of compliance with CLIA requirements and subjected to sanction, our business could be harmed.

Laboratory licensure requirements

We are required to maintain in-state licenses to conduct testing in California and Washington. California and Washington laws establish standards for day-to-day operations of our laboratories in San Francisco and Irvine, and Seattle, respectively. Such laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratories. If our clinical reference laboratories are out of compliance with applicable standards, the appropriate state agency may suspend, restrict or revoke our licenses to operate our clinical reference laboratories, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business. We maintain current licenses in good standing. However, we cannot provide assurance that state regulators will at all times in the future find us to be in compliance with all such laws.

Several states require the licensure of out-of-state laboratories that accept specimens from those states. Our California laboratories hold the required out-of-state laboratory licenses for Maryland, New York, Pennsylvania, and Rhode Island. Our Seattle laboratory holds the required out-of-state laboratory licenses in Maryland, New York, Pennsylvania, and Rhode Island (but not California). Our laboratory in Golden, Colorado holds the required out-of-state laboratory licenses for California, Maryland, Pennsylvania and Rhode Island (but not New York).

In addition to having laboratory licenses in New York, our clinical reference laboratories are also required to obtain approval on a test-specific basis for the tests they run as LDTs by the New York State Department of Health, or NYDOH, before specific testing is performed on samples from New York.

Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of human blood or saliva necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States.

Federal oversight of laboratory developed tests

We provide many of our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by CLIA and state law, respectively).

Historically, the U.S. Food and Drug Administration, or FDA, has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. Subsequently, on January 13, 2017, the FDA published a "discussion paper" in which the agency outlined a substantially revised "possible approach" to the oversight of LDTs. The discussion paper explicitly states that it is not a final version of the 2014 draft guidance and that it does not represent the agency's "formal position;" rather, the discussion paper describes the evolution of the agency's thinking on LDTs, which the agency posted to "spur further dialogue." Notably, in the discussion paper, the agency expressed its willingness to consider "grandfathering" currently marketed LDTs from most or all FDA regulatory requirements.

In August 2020, the U.S. Department of Health and Human Services – the parent agency for FDA – announced that the FDA "will not require premarket review of [LDTs] absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances." It is unclear at this time whether the Biden Administration will rescind or reverse this policy.

It is unclear at this time when, or if, the FDA will finalize its plans to end enforcement discretion (e.g., via notice and comment rulemaking or otherwise), and even then, the new regulatory requirements are expected to be phased-in over time. Nevertheless, the FDA may attempt to regulate certain LDTs on a case-by-case basis at any time.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time-to-time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time.

If the FDA ultimately regulates certain LDTs, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition, and results of operations.

Notwithstanding the FDA's current position with respect to oversight of our tests, we may voluntarily decide to pursue FDA pre-market review for our current tests and/or tests we may offer in the future if we determine that doing so would be appropriate from a strategic perspective – e.g., if CMS indicated that it no longer intended to cover tests offered as LDTs.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

In addition, in November 2013, the FDA issued final guidance regarding the distribution of products labeled for research use only. Certain of the reagents and other products we use in our tests are labeled as research use only products. Certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

Medical device regulatory framework

Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act, or FDCA, the FDA has jurisdiction over medical devices, which are defined to include, among other things, in vitro diagnostics, or IVDs. The FDA regulates the research, design, development, pre-clinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Specifically, for the test we offer that FDA currently regulates as a device, and if the FDA begins to actively regulate LDTs, then for those tests as well, each new or significantly modified test we seek to commercially distribute in the United States could require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a premarket approval, or PMA, application, unless an exemption applies. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Device classification

Under the FDCA, medical devices are classified into one of three classes (Class I, Class II or Class III) depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to General Controls for Medical Devices, which require compliance with the applicable portions of the FDA's Quality System Regulation, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. While some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below, most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These Special Controls can include performance standards, patient registries, FDA guidance documents and postmarket surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk, such as life-supporting, life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent to a legally-marketed predicate device. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The 510(k) clearance process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics, but the information submitted demonstrates that the device is as safe and effective and does not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) premarket notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including data from samples collected in a clinical setting, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III because there is no available predicate device, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the De Novo classification process. The De Novo classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents moderate or low risk. De Novo classification may also be available after receipt of a "not substantially equivalent" letter following submission of a 510(k) to FDA.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by an internal letter-to-file in which the manufacturer documents its reasoning for why a change does not require premarket submission to the FDA. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

The PMA approval process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA clearance or approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facility is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. New PMA applications or PMA supplements may also be required for modifications to any approved diagnostic tests, including modifications to manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

The investigational device process

In the United States, absent certain exceptions, human clinical trials intended to support medical device clearance or approval require an investigational device exemption, or IDE, application. Investigations that meet certain requirements – i.e., involve tests that are labeled investigational use only (IUO), are noninvasive, do not require an invasive sampling procedure that presents significant risk, do not by design or intention introduce energy into a subject, and are not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established product or procedure —are exempt from the IDE requirement. Some types of studies deemed to present “non-significant risk” are deemed to have an approved IDE — without affirmative submission of an IDE application to the FDA — once certain requirements are addressed and Institutional Review Board, or IRB, approval is obtained. If the device presents a “significant risk” to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials.

Where applicable, the IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA’s approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product’s safety and efficacy, even if the trial meets its intended success criteria.

Such clinical trials must be conducted in accordance with the FDA’s IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA for any clinical trials subject to FDA oversight. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a 510(k) premarket notification, for numerous reasons.

The Breakthrough Devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, provided the device also represents breakthrough technology, is one for which no approved or cleared treatment exists, offers significant advantages over existing approved or cleared alternatives, or is one whose availability is in the best interest of patients. All submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed. Although Breakthrough Device designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory clearance or approval for such product.

Research use only, or RUO

In the United States, products labeled and sold for research use only, and not for the diagnosis or treatment of disease, are sold to a variety of parties, including biopharmaceutical companies, academic institutions and molecular labs. Because such products are not intended for use in clinical practice in diagnostics, and the products cannot include clinical or diagnostic claims, they are exempt from many regulatory requirements otherwise applicable to medical devices. In particular, while the FDA regulations require that RUO products be labeled, “For Research Use Only. Not for use in diagnostic procedures,” the regulations do not otherwise subject such products to the FDA’s pre- and post-market controls for medical devices.

A significant change in the laws governing RUO products or how they are enforced may require a change to our RUO products business model in order to maintain compliance. For instance, in November 2013 the FDA issued a guidance document entitled “Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only”, or the RUO Guidance, which highlights the FDA’s interpretation that distribution of RUO products with any labeling, advertising or promotion that suggests that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as a laboratory developed test is in conflict with RUO status. The RUO Guidance further articulates the FDA’s position that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, conflicts with RUO status. If we engage in any activities that the FDA deems to be in conflict with the RUO labeling on the products that we sell, we may be subject to immediate, severe and broad FDA enforcement action that would adversely affect our ability to continue operations selling these products. Accordingly, if the FDA finds that we are distributing RUO products in a manner that is inconsistent with its regulations or guidance, we may be forced to stop distribution of our RUO products until we are in compliance, which would reduce our revenues, increase our costs and adversely affect our business, prospects, results of operations and financial condition. In addition, the FDA’s proposed implementation for a new framework for the regulation of LDTs may negatively impact the LDT market and thereby reduce demand for RUO products. If the FDA requires marketing authorization of our RUO products in the future, there can be no assurance that the FDA will ultimately grant any clearance or approval we request in a timely manner, or at all.

Post-market regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of “off-label” uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA’s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- requesting or requiring recalls, withdrawals, or administrative detention or seizure of our products;
- imposing operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

HIPAA and state privacy, security and breach notification laws

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, the U.S. Department of Health and Human Services issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and requirements for protecting the privacy and security of protected health information (PHI) used or disclosed by covered entities, including most health care providers and their respective business associates, as well as the business associates' subcontractors. Four principal regulations with which we are required to comply have been issued in final form under HIPAA and HITECH: privacy regulations, security regulations, breach notification regulations, and standards for electronic transactions, which establish standards for common healthcare transactions.

The privacy regulations cover the use and disclosure of PHI by covered entities as well as business associates, which are persons or entities that perform certain functions for or on behalf of a covered entity that involve the creation, receipt, maintenance, or transmittal of PHI. Business associates are defined to include a subcontractor to whom a business associate delegates a function, activity, or service, other than in the capacity of the business associate's workforce. As a general rule, a covered entity or business associate may not use or disclose PHI except as permitted or required under the privacy regulations. The privacy regulations also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity or business associate, including the right to access or amend certain records containing his or her PHI, request restrictions on the use or disclosure of his or her PHI, or request an accounting of disclosures of his or her PHI.

Covered entities and business associates also must comply with the security regulations, which establish requirements for safeguarding the confidentiality, integrity, and availability of PHI that is electronically transmitted or electronically stored. In addition, HITECH established, among other things, certain breach notification requirements with which covered entities and business associates must comply. In particular, a covered entity must notify any individual whose unsecured PHI is breached according to the specifications set forth in the breach notification rule. A covered entity must also notify the Secretary of the U.S. Department of Health and Human Services and, under certain circumstances, the media of a breach of unsecured PHI.

There are significant civil and criminal penalties that may be imposed on a covered entity or business associate for violating HIPAA. A covered entity or business associate may also be liable for civil money penalties for a violation that is based on an act or omission of any of its agents, including a downstream business associate, as determined according to the federal common law of agency. Additionally, to the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

The HIPAA privacy, security, and breach notification regulations establish a uniform federal “floor” and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or insofar as such state laws apply to personal information that is broader in scope than PHI as defined under HIPAA. Massachusetts, for example, has a state law that protects the privacy and security of personal information of Massachusetts residents. In addition, every U.S. state has a data breach notification law that requires entities to report certain security breaches to affected consumers and, in some instances, state regulators and consumer reporting agencies. Many states also have laws or regulations that specifically apply to genetic testing and genetic information and are more stringent than the standards under HIPAA. These state genetic information privacy laws include specific informed consent requirements for the conduct of genetic testing and restrict the collection, use, disclosure, or retention of genetic information. Failure to comply with applicable state laws that impose privacy, security, or breach notification requirements for genetic or other personal information could result in significant civil or criminal penalties, administrative actions, or private causes of action by patients, and adversely affect our business, results of operations and reputation.

Federal and state consumer protection laws

The Federal Trade Commission, or FTC, is an independent U.S. law enforcement agency charged with protecting consumers and enhancing competition across broad sectors of the economy. The FTC’s primary legal authority with respect to data privacy and security comes from Section 5 of the FTC Act, which prohibits unfair or deceptive acts or practices in the marketplace. The FTC has increasingly used this broad authority to police data privacy and security, using its powers to investigate and bring lawsuits. Where appropriate, the FTC can seek a variety of remedies, such as but not limited to requiring the implementation of comprehensive privacy and security programs, biennial assessments by independent experts, monetary redress to consumers, and provision of robust notice and choice mechanisms to consumers. In addition to its enforcement mechanisms, the FTC uses a variety of tools to protect consumers’ privacy and personal information, including pursuing enforcement actions to stop violations of law, conducting studies and issuing reports, hosting public workshops, developing educational materials, and testifying before the U.S. Congress on issues that affect consumer privacy.

The vast majority of data privacy cases brought by the FTC fall under the “deceptive” acts prong of Section 5. These cases often involve a failure on the part of a company to adhere to its own privacy and data protection principles set forth in its policies. To avoid Section 5 violations, the FTC encourages companies to build privacy protections and safeguards into relevant portions of their business, and to consider privacy and data protection as the company grows and evolves. In addition, privacy notices should clearly and accurately disclose the type(s) of personal information the company collects, how the company uses and shares that information, and the security measures used by the company to protect that information.

In recent years, the FTC’s enforcement under Section 5 related to data security has included alleged violations of the “unfairness” prong. Many of these cases have alleged that companies were unfair to consumers because they failed to take reasonable and necessary measures to protect consumer data. The FTC has not provided bright line rules defining what constitutes “reasonable and necessary measures” for implementing a cybersecurity program, but it has provided guidance, tips and advice for companies. The FTC has also published past complaints and consent orders, which it urges companies use as guidance to help avoid an FTC enforcement action, even if a data breach or loss occurs.

In addition to the FTC Act, most U.S. states have unfair and deceptive acts and practices statutes, known as UDAP statutes, that substantially mirror the FTC Act and have been applied in the privacy and data security context. These vary in substance and strength from state to state. Many have broad prohibitions against unfair and deceptive acts and practices. These statutes generally allow for private rights of action and are enforced by the states’ Attorneys General.

California Consumer Privacy Act

The California Consumer Privacy Act, or CCPA, is a comprehensive consumer privacy law that took effect on January 1, 2020, and regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of consumers who reside in California. Among other things, the CCPA confers to California consumers the right to receive notice of the categories of personal information that will be collected by a business, how the business will use and share the personal information, and the third parties who will receive the personal information; the CCPA also confers rights to access, delete, or transfer personal information; and the right to receive equal service and pricing from a business after exercising a consumer right granted by the CCPA. In addition, the CCPA allows California consumers the right to opt out of the “sale” of their personal information, which the CCPA defines broadly as any disclosure of personal information to a third party in exchange for monetary or other valuable consideration. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure.

The CCPA does not apply to personal information that is PHI under HIPAA. The CCPA also does not apply to a HIPAA-regulated entity to the extent that the entity maintains patient information in the same manner as PHI. In addition, California amended the law in September 2020 to clarify that de-identified data as defined under HIPAA will also be exempt from the CCPA. Accordingly, we do not have CCPA compliance obligations with respect to most genetic testing and patient information we collect and process. However, we are required to comply with the CCPA insofar as we collect other categories of California consumers’ personal information, such as information about California employees, contractors, and business-to-business contacts. The CCPA provides partial exemptions for employee and business-to-business information that are set to expire on January 1, 2023. In addition, to the extent that we sell or license de-identified information that is derived from California patients’ information, the contracts for the sale or license of such de-identified information will need to include certain provisions required under the CCPA beginning January 1, 2021.

The California Attorney General has had authority to enforce the CCPA and its implementing regulations against covered businesses since July 1, 2020. The CCPA provides for civil penalties for violations, as well as private right of action for data breaches that result from a business’ failure to implement and maintain reasonable data security procedures.

On November 3, 2020, California passed the California Privacy Rights Act (CPRA) through a ballot initiative. The CPRA will create a new California Privacy Protection Agency, an “independent watchdog” whose mission is both to “vigorously enforce” the CPRA and “ensure that businesses and consumers are well-informed about their rights and obligations.” Among other things, the CPRA will create a new category of “sensitive personal information” and offer consumers the right to limit processing of such information, impose purpose limitation, data minimization, data retention, and security compliance obligations on regulated businesses, and add or modify the rights available to consumers, including by providing a right to correct the information a business holds about them. The CPRA’s amendments to the CCPA will take effect on January 1, 2023, and will generally apply to personal information collected by businesses on or after January 1, 2022. The California Attorney General will have authority to begin enforcing the CPRA’s amendments to the CCPA beginning on July 1, 2022.

Privacy and data protection laws

There are a growing number of jurisdictions around the globe that have privacy and data protection laws that may apply to Invitae as it enters or expands its business in jurisdictions outside of the United States. These laws are typically triggered by a company’s establishment or physical location in the jurisdiction, data processing activities that take place in the jurisdiction, and/or the processing of personal information about individuals located in that jurisdiction. Certain international privacy and data protection laws, such as those in the European Union (EU), are more restrictive and prescriptive than those in the U.S., while other jurisdictions may have laws less restrictive or prescriptive than those in the U.S. Enforcement of these laws varies from jurisdiction to jurisdiction, with a variety of consequences, including civil or criminal penalties, litigation, private rights of action or damage to our reputation.

Europe

The EU's General Data Protection Regulation, or GDPR, took effect on May 25, 2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. The GDPR imposes strict requirements on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, which includes sensitive information such as health and genetic information of data subjects. The GDPR also grants individuals various rights in relation to their personal data, including the rights of access, rectification, objection to certain processing and deletion. The GDPR provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, may result in significant administrative fines issued by EU regulators. Maximum penalties for violations of the EU GDPR are capped at 20 million Euros or 4% of an organization's annual global revenue, whichever is greater.

Australia

Australia's federal Privacy Act 1988, or the Privacy Act, and the 13 Australian Privacy Principles, or the APPs, contained in the Privacy Act, apply to government agencies and private sector organizations with annual turnover exceeding AU \$3 million. The Privacy Act extends to all of Australia's external territories, but also applies to an act done, or practice engaged in, or outside Australia (and Australia's external territories) by an organization, or small business operator, that has a link to Australia, such as a continued presence, partnership, incorporation, central management and control, or citizenship in Australia. An organization may also have a link to Australia if the organization conducts business in Australia and collects or stores personal information in Australia. The Privacy Act applies to any collection, holding, use or disclosure of personal information by a regulated entity, with enhanced protections for sensitive information such as genetic information. The Privacy Act prescribes certain rights for individuals, including rights to know why the information is collected, how it is used, and to whom it is disclosed, the right of the individual not to identify themselves in certain circumstances, the right of access, the right to stop receiving unwanted direct marketing, the right to correct information, and the right to make a complaint. Australia's Privacy Commissioner enforces the Privacy Act and any acts that may violate an individual's privacy. The Privacy Commissioner can levy significant fines on individuals and corporations that violate the Privacy Act.

Canada

Canada has several federal, provincial and territorial privacy statutes that govern the protection of personal information. The Personal Information Protection and Electronic Documents Act 2000, or PIPEDA, applies to the collection, use, and disclosure of personal information in the course of commercial activities in Canada. Although PIPEDA is silent with respect to its extraterritorial application, the Federal Court of Canada has concluded that PIPEDA applies to businesses established in other jurisdictions if there is a "real and substantial connection" between the organization's activities and Canada. PIPEDA and provincial data protection laws require specific notices regarding openness and transparency and require regulated organizations to obtain consent in order to process such information. Canadian individuals enjoy rights of access and to correct inaccuracies. Violations of Canadian data protection laws can result in significant fines.

India

The Indian Constitution was recently interpreted to include a fundamental right to privacy. In addition, India's laws and regulations address specific sectoral data protection concerns. The Information Technology Act 2000, as amended, or the IT Act, is the primary national law regulating the collection and use of personal information that is sensitive. The IT Act applies to corporations and other "body corporates" that possess, maintain, or otherwise process personal information, including body corporates that act on behalf of other body corporates. Certain provisions of the IT Act provide liability for negligent handling of personal information. For example, the IT Act provides that any corporation or other body corporate that handles sensitive personal data is liable to pay damages for any loss caused by its negligence in implementing and maintaining reasonable security practices and procedures.

In addition, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules 2011, or the Data Privacy Rules, issued under the IT Act regulate the use of personal information and sensitive personal data. The Data Privacy Rules mandate that businesses have a privacy policy, obtain consent when collecting or transferring personal information, and inform the data subject about any recipients of that data. The IT Act includes a private right of action for individuals, and authorizes criminal punishment (with a fine, three years in prison, or both) for disclosing personal information without the consent of the data subject or in breach of any relevant contract.

Israel

Israel's data protection regime is governed primarily by the Protection of Privacy Law and the regulations promulgated under it, or the PPL, and the guidelines of the Israeli regulator, the Privacy Protection Authority, or the PPA. The PPL applies to: (1) database owners, database holders, and database managers based in Israel; and (2) data processing operations that take place in Israel, regardless of whether the individuals about whom the data relates are residents or citizens of Israel. The PPL could also be interpreted to apply to non-Israeli database owners, database holders, or database managers that process personal information about Israeli residents or citizens when such processing takes place outside of Israel. Various regulations promulgated under the PPL by the PPA set out rules and procedures for data security, data retention, data subject rights, and cross border transfers of data. These regulations also do not clearly state their jurisdictional scope, such that there is a risk they could be interpreted as applying to foreign-based entities that process data about Israeli citizens.

The PPA is required to maintain a registry of databases and is empowered to supervise compliance with and investigate alleged violations of the PPL and related regulations. The PPA may impose administrative fines for violations of the PPL and related regulations, and willful violations may result in criminal liability and up to five years in prison. A breach of privacy is also actionable, and an individual claimant may obtain monetary compensation or injunctive relief. A court may award statutory damages without proof of damages for breach of privacy rights. If the breach was intentional, the damages may be doubled. The PPL also specifies that an act or omission in breach of certain of its provisions, such as failure to ensure data security, may give rise to a tort claim.

Japan

Japan's primary data protection law, the Act on the Protection of Personal Information, or APPI, was recently amended to include GDPR-like requirements, including additional transparency requirements, data transfer obligations, enhanced data breach notification requirements, additional data subject rights and stronger penalties for violations, including significant fines. The amendment clarifies that its provisions, obligations and penalties apply to entities outside of Japan that supply goods or services in Japan and handle personal information from an individual in Japan.

Information Blocking Prohibition

On May 1, 2020, the Office of the National Coordinator for Health Information Technology promulgated final regulations under the authority of the 21st Century Cures Act to impose new conditions to obtain and maintain certification of certified health information technology and prohibit certain covered actors, including developers of certified health information technology, health information networks / health information exchanges, and health care providers, from engaging in activities that are likely to interfere with the access, exchange, or use of electronic health information (information blocking). The final regulations further defined exceptions for activities that are permissible, even though they may have the effect of interfering with the access, exchange, or use of electronic health information. The information blocking effective date is April 5, 2021. Under the 21st Century Cures Act, health care providers that violate the information blocking prohibition will be subject to appropriate disincentives, which the U.S. Department of Health and Human Services has yet to establish through required rulemaking. Developers of certified information technology and health information networks / health information exchanges, however, may be subject to civil monetary penalties of up to \$1 million per violation. The U.S. Department of Health and Human Services Office of Inspector General has the authority to impose such penalties and on April 24, 2020 published a proposed rule to codify new authority in regulation, which the agency proposed would be effective 60 days after it issues a final rule, but in no event before November 2, 2020. The U.S. Department of Health and Human Services Office of Inspector General has not yet issued a final rule.

Federal, state and foreign fraud and abuse laws

In the United States, there are various fraud and abuse laws with which we must comply, and we are potentially subject to regulation by various federal, state and local authorities, including CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, and individual U.S. Attorney offices within the Department of Justice, and state and local governments. We also may be subject to foreign fraud and abuse laws.

In the United States, the federal Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering of any good, facility, service or item for which payment may be made in whole or in part by a federal healthcare program. Many courts have held that the Anti-Kickback Statute may be violated if any one purpose of the remuneration is to induce or reward patient referrals or other federal healthcare program business, regardless of whether there are other legitimate purposes for the arrangement. The definition of “remuneration” has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, consulting fees, waivers of co-payments, ownership interests, and providing anything at less than its fair market value. The Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry. The Anti-Kickback Statute includes several statutory exceptions, and the U.S. Department of Health and Human Services has issued a series of regulatory “safe harbors.” These exceptions and safe harbor regulations set forth certain requirements for various types of arrangements, which, if met, will protect the arrangement from potential liability under the Anti-Kickback Statute. Although full compliance with the statutory exceptions or regulatory safe harbors ensures against liability under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific statutory exception or regulatory safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. Penalties for violations of the Anti-Kickback Statute are severe, and include imprisonment, criminal fines, civil money penalties, and exclusion from participation in federal healthcare programs. Many states also have anti-kickback statutes, some of which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

There are also federal laws related to healthcare fraud and false statements, among others, that apply to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payer programs such as the Medicare and Medicaid programs. The false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payer programs.

Another development affecting the healthcare industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act’s “whistleblower” or “qui tam” provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payer program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by presenting or causing to be presented a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each false claim. For penalties assessed after June 19, 2020, whose associated violations occurred after November 2, 2015, the penalties range from \$11,665 to \$23,331 for each false claim. The minimum and maximum per claim penalty amounts are subject to annual increases for inflation.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and some of these state laws apply where a claim is submitted to any third-party payer and not only a governmental payer program.

Additionally, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have knowingly presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or for a claim that is false or fraudulent. This law also prohibits the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for items or services reimbursable by Medicare or a state healthcare program. There are several exceptions to the prohibition on beneficiary inducement.

The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs, to include private insurance (i.e., it is an "all payer" statute). For purposes of EKRA, the term "laboratory" is defined broadly and without reference to any connection to substance use disorder treatment. EKRA is a criminal statute and violations can result in fines of up to \$200,000, up to 10 years in prison, or both, per violation. The law includes a limited number of exceptions, some of which closely align with corresponding federal Anti-Kickback Statute exceptions and safe harbors and others that materially differ.

We are also subject to the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. In Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act 2010, faces imprisonment of up to ten years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, also imposed annual reporting requirements on entities including manufacturers of certain devices, medical supplies, drugs and biologics for certain payments and transfers of value that the manufacturer provides, directly or indirectly, to or on behalf of certain types of health care providers, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as defined by such law as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year. The Physician Payments Sunshine Act also requires entities including applicable manufacturers to report certain ownership and investment interests held by such physicians and their immediate family members in such manufacturers. In addition, certain states, such as Vermont and Massachusetts, have enacted laws that impose certain reporting requirements for payments and transfers of value provided to covered healthcare providers. These state laws are not preempted by the federal Physician Payments Sunshine Act to the extent the state law requires the reporting of information that is not required to be reported under the federal Physician Payments Sunshine Act. Finally, certain states such as Massachusetts, Nevada, and Vermont have enacted laws that limit or prohibit the provision of payments or other transfers of value to covered recipients, such as certain health care providers, hospitals, and health benefit plan administrators.

Physician referral prohibitions

A federal law directed at “self-referrals,” commonly known as the “Stark Law,” prohibits a physician from referring a patient to an entity for certain Medicare-covered designated health services, including laboratory services, if the physician, or an immediate family member, has a financial relationship with the entity, unless an exception applies. The Stark Law also prohibits an entity from billing for services furnished pursuant to a prohibited referral. A physician or entity that engages in a scheme to circumvent the Stark Law’s referral prohibition may be fined up to \$172,137 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to civil monetary penalties of up to \$25,820 per service, an assessment of up to three times the amount claimed and possible exclusion from participation in federal healthcare programs. Bills submitted in violation of the Stark Law may not be paid by Medicare, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states have comparable laws that apply to services covered by other third-party payers. The Stark Law also prohibits state receipt of federal Medicaid matching funds for services furnished pursuant to a prohibited referral. This provision of the Stark Law has not been implemented by regulations, but some courts have held that the submission of claims to Medicaid that would be prohibited as self-referrals under the Stark Law for Medicare could implicate the False Claims Act.

Corporate practice of medicine

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging clinicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. For example, California’s Medical Board has indicated that determining what diagnostic tests are appropriate for a particular condition and taking responsibility for the ultimate overall care of the patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings.

Intellectual property

We rely on a combination of intellectual property rights, including trade secrets, copyrights, trademarks, customary contractual protections and, to a lesser extent, patents, to protect our core technology and intellectual property. With respect to patents, we believe that the practice of patenting individual genes, along with patenting tools and methods specific to individual genes, has impeded the progress of the genetic testing industry beyond single gene tests and is antithetical to our core principle that patients should own and control their own genomic information. The U.S. Supreme Court has issued a series of unanimous (9-0) decisions setting forth limits on the patentability of natural phenomena, natural laws, abstract ideas and their applications — *i.e.*, *Mayo Collaborative v. Prometheus Laboratories (2012)*, or *Mayo, Association for Molecular Pathology v. Myriad Genetics (2013)*, or *Myriad*, and *Alice Corporation v. CLS Bank (2014)*, or *Alice*. As discussed below, we believe the *Mayo*, *Myriad* and *Alice* decisions bring clarity to the limits to which patents may cover specific genes, mutations of such genes, or gene-specific technology for determining a patient’s genomic information.

Patents

U.S. Supreme Court cases have clarified that naturally occurring DNA sequences are natural phenomena, which should not be patentable. On June 13, 2013, the U.S. Supreme Court decided *Myriad*, a case challenging the validity of patent claims held by Myriad relating to the cancer genes BRCA1 and BRCA2. The *Myriad* Court held that genomic DNAs that have been isolated from, or have the same sequence as, naturally occurring samples, such as the DNA constituting the BRCA1 and BRCA2 genes or fragments thereof, are not eligible for patent protection. Instead, the *Myriad* Court held that only those complementary DNAs (cDNAs) which have a sequence that differs from a naturally occurring fragment of genomic DNA may be patent eligible. Because it will be applied by other courts to all gene patents, the holding in *Myriad* also invalidates patent claims to other genes and gene variants. Prior to *Myriad*, on August 16, 2012, the U.S. Court of Appeals for the Federal Circuit had held that certain patent claims of Myriad directed to methods of comparing or analyzing BRCA1 and BRCA2 sequences to determine whether or not a person has a variant or mutation are unpatentable abstract processes, and Myriad did not appeal such ruling.

We do not currently have any patents or patent applications directed to the sequences of specific genes or variants of such genes, nor do we rely on any such in-licensed patent rights of any third party. We believe that correlations between specific gene variants and a person's susceptibility to certain conditions or diseases are natural laws that are not patentable under the U.S. Supreme Court's decision in *Mayo*. The *Mayo* case involved patent claims directed to optimizing, on a patient-specific basis, the dosage of a certain drug by measuring its metabolites in a patient. The *Mayo* Court determined that patent claims directed at detection of natural correlations, such as the correlation between drug metabolite levels in a patient and that drug's optimal dosage for such patient, are not eligible for patent protection. The *Mayo* Court held that claims based on this type of comparison between an observed fact and an understanding of that fact's implications represent attempts to patent a natural law and, moreover, when the processes for making the comparison are not themselves sufficiently inventive, claims to such processes are similarly patent-ineligible. On June 19, 2014, the U.S. Supreme Court decided *Alice*, where it amplified its *Mayo* and *Myriad* decisions and clarified the analytical framework for distinguishing between patents that claim laws of nature, natural phenomena and abstract ideas and those that claim patent-eligible applications of such concepts. According to the *Alice* Court, the analysis depends on whether a patent claim directed to a law of nature, a natural phenomenon or an abstract idea contains additional elements, an "inventive concept," that "is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself;" (citing *Mayo*).

We believe that *Mayo*, *Myriad* and *Alice* not only render as unpatentable genes, gene fragments and the detection of a person's sequence for a gene, but also have the same effect on generic applications of conventional technology to specific gene sequences. For example, we believe that generic claims to primers or probes directed to specific gene sequences and uses of such primers and probes in determining a person's genetic information are not patentable. We do not currently have any patents or patent applications directed to such subject matter nor have we in-licensed such patents rights of any third party.

Unlike patents directed to specific genes, we do rely upon, in part, patent protection to protect technology that is not gene-specific and that provides us with a potential competitive advantage as we focus on making comprehensive genetic information less expensive and more broadly available to our customers. In this regard, we have issued U.S. patents, pending U.S. patent applications and corresponding non-U.S. patents and patent applications directed to various aspects of our laboratory, analytic and business practices. We intend to pursue further patent protection where appropriate.

For information regarding legal actions that pertain to intellectual property rights, see Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this report.

Trade secrets

In addition to seeking patent protection for some of our laboratory, analytic and business practices, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain and develop our competitive position. We have developed proprietary procedures for both the laboratory processing of patient samples and the analysis of the resulting data to generate clinical reports. For example, we have automated aspects of our processes for curating information about known variants, identifying variants in an individual's sequence information, associating those variants with known information about their potential effects on disease, and presenting that information for review by personnel responsible for its interpretation and for the delivery of test reports to clinicians and patients. We try to protect these trade secrets, in part, by taking reasonable steps to keep them confidential. This includes entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees and certain third parties. We also enter into invention or patent assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we may not enter into such agreements with all relevant parties, and these parties may not abide by the terms of their agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy or independently develop and commercially exploit aspects of our technology or obtain and use information that we regard as proprietary.

Trademarks

We work hard to achieve a high level of quality in our operations and to provide our customers with a superior experience when interacting with us. As a consequence, our brand is very important to us, as it is a symbol of our reputation and representative of the goodwill we seek to generate with our customers. As a consequence, we have invested significant resources in protection of our trademarks.

Environmental matters

Our operations require the use of hazardous materials (including biological materials) that subject us to a variety of federal, state and local environmental and safety laws and regulations. Some of these regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or new regulations will affect our business, operations or the cost of compliance.

Raw materials and suppliers

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Agena Bioscience, Inc., Illumina, Inc., Integrated DNA Technologies Incorporated, Roche Holdings Ltd., QIAGEN, Inc. and Twist Bioscience Corporation for certain laboratory reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We are in active litigation with affiliates of QIAGEN, Inc. as described in Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this report. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers and QIAGEN, Inc. to provide the enzymes that we use in our products. Our operations could be interrupted if we encounter delays or difficulties in securing these reagents and enzymes, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our operations, including sequencers and various associated reagents and enzymes. The use of equipment or materials provided by these replacement suppliers would require us to alter our operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot be certain that we will be able to secure alternative equipment, reagents and other materials, or bring such equipment, reagents and materials on line and revalidate them without experiencing interruptions in our workflow. If we encounter delays or difficulties in securing, reconfiguring or revalidating equipment and materials, our business and reputation could be adversely affected.

Customer concentration and seasonality

We receive payment for our products and services from patients, biopharmaceutical partners, third-party payers and other business-to-business customers. As of December 31, 2020, our revenue has been primarily derived from test reports generated from our assays. See information regarding our customer concentration in Note 2, "Summary of significant accounting policies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

We have historically experienced higher revenue in our fourth quarter compared to other quarters in our fiscal year due in part to seasonal demand of our tests from patients who have met their annual insurance deductible. However, changes in our product and payer mix might cause these historical seasonal patterns to be different than future patterns of revenue or financial performance.

Human capital resources

Our mission

The strength of our team and the culture in which we work is essential to our ability to achieve our broader mission. Attracting, developing and retaining exceptional employees is vitally important to us, but we also invest in creating a differentiated culture for our team that enables continuous innovation at scale. We want Invitae to be a force for good, a team that is helping make genetics and healthcare equally accessible to all. We had approximately 2,100 employees as of December 31, 2020, of which approximately 55% are women and 45% men.

Our employee engagement and culture

Our hiring process has been designed to provide an equitable candidate experience, facilitate the inclusion of new perspectives, foster innovation and creativity, and leverage technology and data analytics to address gaps in representation. In 2020 we established a Diversity, Equity and Inclusion, or DEI, roadmap. Our vision is to cultivate a place where we all belong. Our DEI mission is to engage, develop and retain talent from diverse backgrounds by fostering community, providing education and support, and advancing inclusive research and health equity globally. As of December 2020, excluding employees who joined us through our acquisition of ArcherDX in October 2020, approximately 59% of our workforce was White, 20% Asian, 8% Hispanic, 5% two or more races (not Hispanic or Latino), and 4% Black or African American.

We are committed to maintaining and improving the health and safety of our employees. As per our Code of Business Conduct and Ethics, all employees have responsibility for maintaining a safe and healthy workplace for all other employees by following our safety and health rules, policies and practices and reporting accidents, injuries and unsafe equipment, practices or conditions. In addition, we established a Crisis Management Team that, along with the Employee Health and Safety Administrator, comprise the Steering Committee for pandemic response.

We empower our employees to own their career path and seek out training programs to take them to the next level. We are currently in the process of developing a structure of growth opportunities and ways to understand and communicate pathways. We have also invested in our training and development programs and infrastructure for our employees.

As part of our commitment to data-driven decision making, we conduct an ongoing monthly survey that asks our teammates three key questions: how they feel about the company direction, what's going well and what's not going well. We've been asking these questions consistently for several years so we can quickly identify trends as they emerge. We believe this combination of ongoing pulse surveys to help detect timely changes in team morale and engagement, and occasional deep dives for a more complete picture, allows our management and Talent Operations to better understand team dynamics and make changes to policies, benefits and organizational structure to respond to current challenges. It allows us to quickly gather feedback on what's working and what's not.

Information about our Executive Officers

The names of our executive officers and other corporate officers, and their ages as of February 26, 2021, are as follows:

Name	Age	Position
Sean E. George, Ph.D.	47	President, Chief Executive Officer, Director and Co-Founder
Thomas R. Brida	50	General Counsel and Secretary
Shelly D. Guyer	60	Chief Financial Officer
Kenneth D. Knight	60	Chief Operating Officer
Robert L. Nussbaum, M.D.	71	Chief Medical Officer
Katherine A. Stueland	45	Chief Commercial Officer
Robert F. Werner	47	Chief Accounting Officer

Sean E. George, Ph.D. is one of our co-founders and has been our President and Chief Executive Officer since January 2017, a position he also held from January 2010 through August 2012. Dr. George also served as our President since August 2012 and he served as our Chief Operating Officer from August 2012 until January 2017. He has also served as a director since January 2010. Prior to co-founding Invitae, Dr. George served as Chief Operating Officer from 2007 to November 2009 at Navigenics, Inc., a personalized medicine company. Previously, he served as Senior Vice President of Marketing and Senior Vice President, Life Science Business at Affymetrix, Inc., a provider of life science and molecular diagnostic products, as well as Vice President, Labeling and Detection Business at Invitrogen Corporation, a provider of tools to the life sciences industry, during his tenure there from 2002 to 2007. Dr. George currently serves as a director of CM Life Sciences, Inc., a publicly traded special purpose acquisition company. Dr. George holds a B.S. in Microbiology and Molecular Genetics from the University of California Los Angeles, an M.S. in Molecular and Cellular Biology from the University of California Santa Barbara, and a Ph.D. in Molecular Genetics from the University of California Santa Cruz.

Thomas R. Brida has served as our General Counsel since January 2017. Mr. Brida also served as our Deputy General Counsel from January 2016 to January 2017. Prior to joining Invitae, he was Associate General Counsel at Bio-Rad Laboratories, a life science research and clinical diagnostics manufacturer, from January 2004 to January 2016. He holds a B.A. from Stanford University and a J.D. from the U.C. Berkeley School of Law.

Shelly D. Guyer has served as our Chief Financial Officer since June 2017. On November 5, 2020, we announced that Ms. Guyer will be transitioning to a new role leading our sustainability efforts, including our ESG (environmental, social and governance) initiatives. She will continue to serve as Chief Financial Officer while the Company conducts a search for her successor. Ms. Guyer served as Chief Financial Officer of Veracyte, Inc., a genomic diagnostics company, from April 2013 to December 2016 and served as Veracyte's Secretary from April 2013 to March 2014. Previously, she served as Chief Financial Officer and Executive Vice President of Finance and Administration of iRhythm Technologies, Inc., a digital healthcare company, from April 2008 to December 2012. From March 2006 to August 2007, Ms. Guyer served as Vice President of Business Development and Investor Relations of Nuvelo, Inc., a biopharmaceutical company. Prior to joining Nuvelo, Ms. Guyer worked at J.P. Morgan Securities and its predecessor companies for over 17 years, serving in a variety of roles including in healthcare investment banking and four years with the H&Q Environmental Technology Fund. Ms. Guyer currently serves as a director and chair of the audit committee of NGM Biopharmaceuticals, Inc., a publicly held biopharmaceutical company. Ms. Guyer holds an A.B. in Politics from Princeton University and an M.B.A. from the Haas School of Business at the University of California Berkeley.

Kenneth D. Knight has served as our Chief Operating Officer since June 2020. Prior to that, he most recently served as Vice President of transportation services at Amazon.com, Inc., a multinational and diversified technology company, from December 2019 to June 2020, and as Vice President of Amazon's global delivery services, fulfillment operations and human resources from April 2016 to December 2019. Prior to his time at Amazon, from 2012 to March 2016, Mr. Knight served as general manager of material handling and underground business division at Caterpillar Inc., a manufacturer of machinery and equipment. Prior to that, Mr. Knight served in various capacities at General Motors Company, a vehicle manufacturer, for 27 years, including as executive director of global manufacturing engineering and as manufacturing general manager. Mr. Knight holds a B.S. in Electrical Engineering from the Georgia Institute of Technology and a Master of Business Administration from the Massachusetts Institute of Technology.

Robert L. Nussbaum, M.D. has served as our Chief Medical Officer since August 2015. From April 2006 to August 2015, he was chief of the Division of Genomic Medicine at UCSF Health where he also held leadership roles in the Cancer Genetics and Prevention Program beginning in January 2009 and the Program in Cardiovascular Genetics beginning in July 2007. From April 2006 to August 2015, he served as a member of the UCSF Institute for Human Genetics. Prior to joining UCSF Health, Dr. Nussbaum was chief of the Genetic Disease Research Branch of the National Human Genome Research Institute, one of the National Institutes of Health, from 1994 to 2006. He is a member of the National Academy of Medicine and a fellow at the American Academy of Arts and Sciences. Dr. Nussbaum is a board-certified internist and medical geneticist who holds a B.S. in Applied Mathematics from Harvard College and an M.D. from Harvard Medical School in the Harvard-MIT joint program in Health Sciences and Technology. He completed his residency in internal medicine at Barnes-Jewish Hospital and a fellowship in medical genetics at the Baylor College of Medicine.

Katherine A. Stueland has served as our Chief Commercial Officer since October 2016. From January 2014 to October 2016, she served as our head of communications and investor relations. Prior to joining Invitae, Ms. Stueland was a Principal at Vivo Communications, a healthcare communications company, from January 2013 to December 2013. Previously, she served as Vice President, Communications and Investor Relations at Dendreon Corporation, a biotechnology company. Ms. Stueland holds a B.S. in English Literature from Miami University in Ohio.

Robert F. Werner has served as our Chief Accounting and Principal Accounting Officer since May 2020. Prior to that, Mr. Werner served as our Corporate Controller from September 2017. Prior to joining Invitae, from February 2015 to September 2017, Mr. Werner served as Vice President of Finance and Corporate Controller of Proteus Digital Health, Inc., a digital medicine pharmaceuticals company. Prior to that, Mr. Werner served as Corporate Controller and Principal Accounting Officer of CardioDx, Inc., a molecular diagnostics company, from March 2012 to February 2015. Mr. Werner is a Certified Public Accountant and started his career at Ernst & Young LLP. Mr. Werner holds a Bachelor of Science in Accounting and a Master of Accountancy in Professional Accounting from Brigham Young University's Marriott School of Management.

General Information

We were incorporated in the State of Delaware on January 13, 2010 under the name Locus Development, Inc. and changed our name to Invitae Corporation in 2012.

Our principal executive offices are located at 1400 16th Street, San Francisco, California 94103, and our telephone number is (415) 374-7782. Our website address is www.invitae.com. The information contained on, or that can be accessed through, our website is not part of this annual report on Form 10-K.

We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC. You may obtain a free copy of these reports in the Investor Relations section of our website, www.invitae.com. All reports that we file are also available at www.sec.gov.

ITEM 1A. Risk Factors.

Risks related to our business and strategy

We face risks related to health epidemics, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

Our business has been and could continue to be adversely affected by a widespread outbreak of contagious disease, including the recent pandemic of respiratory illness caused by a novel coronavirus known as COVID-19. Global health concerns relating to COVID-19 have negatively affected the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty.

The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. For example, some of our personnel located at our headquarters and other offices in California, elsewhere in the United States and in other countries, have been subject to shelter-in-place or stay-at-home orders from state and local governments. These measures have adversely impacted and may further impact our employees and operations and the operations of our customers, suppliers and business partners, and may continue to negatively impact spending patterns, payment cycles and insurance coverage levels. These measures have adversely affected and may continue to adversely affect demand for our tests. Earlier this year, many of our customers, including hospitals and clinics, suspended non-emergency appointments and services, which resulted in a significant decrease in our test volume. Travel bans, restrictions and border closures have also impacted our ability to ship tests to and receive samples from our customers. Some of these measures by government authorities have and may continue to remain in place for a significant period of time. Even if these measures are lifted, they may be implemented again if COVID-19 is not contained or returns, as has been the case recently. These measures have adversely affected and may continue to adversely affect our test volume, sales activities and results of operations.

The spread of COVID-19 has caused us to modify our business practices (including employee travel, mandating that all non-essential personnel work from home, temporary closures of our offices, cancellation of physical participation in sales activities, meetings, events and conferences and increasing inventories of certain supplies because, although we have not experienced significant disruption in our supply chain, over the past several months, we have experienced supply delays as a result of the COVID-19 pandemic and have also had to obtain supplies from new suppliers), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers and business partners. Such actions could also impact our ability to fully integrate businesses we have acquired and those we may acquire in the future. There is no certainty that such actions will be sufficient to mitigate the risks posed by the virus or otherwise be satisfactory to government authorities. If significant portions of our workforce are unable to work effectively, including due to illness, quarantines, social distancing, government actions or other restrictions in connection with COVID-19, our operations will be impacted.

The extent to which COVID-19 continues to impact our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration and spread of the pandemic, the actions to contain the virus and treat its impact, and how quickly and to what extent normal economic and operating activities can resume. COVID-19 could limit the ability of our customers, suppliers and business partners to perform, including third-party payers' ability to make timely payments to us during and following the pandemic. We have also experienced and may continue to experience a shortage of, or delays in, laboratory supplies and equipment, or a suspension of services from other laboratories or third parties. Even after COVID-19 has subsided, we may continue to experience an adverse impact to our business as a result of its global economic impact, including any recession that has occurred or may occur in the future, and loss of health insurance coverage resulting from pandemic-related job losses.

Specifically, difficult macroeconomic conditions, such as decreases in per capita income and level of disposable income, increased and prolonged unemployment or a decline in consumer confidence as a result of COVID-19, as well as limited or significantly reduced points of access of our tests, could have a material adverse effect on the demand for our tests. Under difficult economic conditions, consumers may seek to reduce discretionary spending by forgoing our tests. Decreased demand for our tests, particularly in the United States, has negatively affected and could continue to negatively affect our overall financial performance. Because a significant portion of our revenue is concentrated in the United States, where the impact of COVID-19 has been significant, COVID-19 has had and could continue to have a disproportionately negative impact on our business and financial results.

There are no comparable recent events which may provide guidance as to the effect of the spread of COVID-19 and a pandemic, and, as a result, the ultimate impact of COVID-19 or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of COVID-19's impact on our business, our operations, or the global economy as a whole. However, the effects could have a material impact on our results of operations, and we continue to monitor the situation closely.

To the extent the COVID-19 pandemic continues to adversely affect our business and financial results, it may also have the effect of heightening many of the other risks described in this section.

We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.

We have incurred substantial losses since our inception. For the years ended December 31, 2020, 2019 and 2018, our net losses were \$602.2 million, \$242.0 million and \$129.4 million, respectively. At December 31, 2020, our accumulated deficit was \$1.4 billion. While our revenue has increased over time, we expect to continue to incur significant losses as we invest in our business. We incurred research and development expenses of \$240.6 million, \$141.5 million and \$63.5 million in 2020, 2019 and 2018, respectively, and selling and marketing expenses of \$168.3 million, \$122.2 million and \$74.4 million in 2020, 2019 and 2018, respectively. We expect these losses may increase as we focus on scaling our business and operations and expanding our testing capabilities, which may also increase our operating expenses, and we have experienced and may continue to experience decreases in test volume due to the impact of COVID-19. In addition, as a result of the integration of acquired businesses, we may be subject to unforeseen or additional expenditures, costs or liabilities, including costs and potential liabilities associated with litigation. Our prior losses and expected future losses have had and may continue to have an adverse effect on our stockholders' equity, working capital and stock price. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We began operations in January 2010 and commercially launched our initial assay in late November 2013; accordingly, we have a relatively limited operating history upon which you can evaluate our business and prospects. Our limited commercial history makes it difficult to evaluate our current business and makes predictions about our future results, prospects or viability subject to significant uncertainty. Our prospects must be considered in light of the risks and difficulties frequently encountered by companies in their early stage of development, particularly companies in new and rapidly evolving markets such as ours. These risks include an evolving and unpredictable business model and the management of growth. To address these risks, we must, among other things, increase our customer base; continue to implement and successfully execute our business and marketing strategy; identify, acquire and successfully integrate companies, assets or technologies in areas that are complementary to our business strategy; successfully enter into other strategic collaborations or relationships; obtain access to capital on acceptable terms and effectively utilize that capital; identify, attract, hire, retain, motivate and successfully integrate additional employees; continue to expand, automate and upgrade our laboratory, technology and data systems; obtain, maintain and expand coverage and reimbursement by healthcare payers; provide rapid test turnaround times with accurate results at low prices; provide superior customer service; and respond to competitive developments. We cannot assure you that we will be successful in addressing these risks, and the failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure, commercial operations, research and development and selling and marketing activities and pursue and integrate acquisitions. We believe our existing cash and cash equivalents as of December 31, 2020, including the net proceeds from our recent public offering and revenue from sales of our tests will be sufficient to meet our anticipated cash requirements for our currently-planned operations for the foreseeable future. We may raise additional capital to finance operations prior to achieving profitability, or should we make additional acquisitions. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. In addition, the terms of our credit agreement restrict our ability to incur certain indebtedness and issue certain equity securities. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings, if available, could impose significant restrictions on our operations.

The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, selling and marketing initiatives, or potential acquisitions. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to our company.

We have acquired and may continue to acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.

As part of our business strategy, we have pursued and expect to continue to pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. Since 2017, we have acquired several companies, including companies in family health genetic information services, the patient data collection industry, the non-invasive prenatal screen offering industry, the genetic information industry and the use of artificial intelligence in such industry, the pharmacogenetic testing industry, and the oncology industry.

With respect to our acquired businesses and any acquisitions we may make in the future, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. For example, if we are unable to integrate ArcherDX's technology, people and distributed products business model into our existing business, we will not realize the expected benefits of that acquisition. Any acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Furthermore, as we experienced in the past, the loss of customers, payers, partners or suppliers following the completion of any acquisitions by us could harm our business. Changes in services, sources of revenue, and branding or rebranding initiatives may involve substantial costs and may not be favorably received by customers, resulting in an adverse impact on our financial results, financial condition and stock price. Integration of an acquired company or business also may require management's time and resources that otherwise would be available for ongoing development of our existing business. We may also need to divert cash from other uses to fund these integration activities and these new businesses. Ultimately, we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment, or these benefits may take longer to realize than we expected.

In connection with certain of our completed acquisitions, we have agreed to pay cash and/or stock consideration that is contingent upon the achievement of specified objectives, such as development objectives, regulatory submissions, regulatory approvals and revenue recognized related to certain products. As of the date of the applicable acquisition, we record a contingent liability representing the estimated fair value of the contingent consideration we expect to pay. On a quarterly basis, we reassess these obligations and, in the event our estimate of the fair value of the contingent consideration changes, we recorded increases or decreases in the fair value as an adjustment to operating expense, which could have a material impact on our results of operations. As of December 31, 2020, we accrued \$796.6 million of contingent consideration, most of which related to potential milestone payments in the form of our common stock in connection with our acquisition of ArcherDX. In addition, our actual payments may differ materially from the amount of the contingent liability, which could have a material impact on our results of operations.

To finance any acquisitions or investments, we may raise additional funds, which could adversely affect our existing stockholders and our business, as discussed in the preceding risk factor. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. In addition, our stockholders may experience substantial dilution as a result of additional securities we may issue for acquisitions. Open market sales of substantial amounts of our common stock issued to stockholders of companies we acquire could also depress our stock price. Additional funds may not be available on terms that are favorable to us, or at all.

If third-party payers, including managed care organizations, private health insurers and government health plans do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.

Our ability to increase the number of billable tests and our revenue will depend on our success achieving reimbursement for our tests from third-party payers. Reimbursement by a payer may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary, cost-effective and has received prior authorization. The commercial success of our distributed products, including STRATAFIDE, a pan-solid tumor in vitro diagnostic, or IVD, and our Personalized Cancer Monitoring product, or PCM, if approved, will depend on the extent to which our customers receive coverage and adequate reimbursement from third-party payers, including as managed care organizations and government payers (e.g., Medicare and Medicaid).

Since each payer makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payer to cover and the amount it will reimburse for our tests will likely be made on an indication by indication basis. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our tests from most of the large commercial third-party payers in the United States, and the Centers for Medicare & Medicaid Services, or CMS, provides reimbursement for our multi-gene tests for hereditary breast and ovarian cancer-related disorders as well as colon cancer. We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from third-party payers may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive and may not result in payment. In cases where there is not a contracted rate for reimbursement, there is typically a greater coinsurance or copayment requirement from the patient, which may result in further delay or decreased likelihood of collection.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payer to payer, and we have needed additional time and resources to comply with them. We have also experienced, and may continue to experience, delays in or denials of coverage if we do not adequately comply with these requirements. Our third-party payers have also requested, and in the future may request, audits of the amounts paid to us. We have been required to repay certain amounts to payers as a result of such audits, and we could be adversely affected if we are required to repay other payers for alleged overpayments due to lack of compliance with their reimbursement policies. In addition, we have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests and any future tests we may develop or acquire. If we fail to expand and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the market. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.

With the development of next generation sequencing, the clinical genetics market is becoming increasingly competitive, and we expect this competition to intensify in the future. We face competition from a variety of sources, including:

- dozens of relatively specialized competitors focused on genetics applied to healthcare, such as Ambry Genetics, a subsidiary of Konica Minolta Inc.; Athena Diagnostics and Blueprint Genetics, subsidiaries of Quest Diagnostics Incorporated; Baylor-Miraca Genetics Laboratories; Caris Life Sciences, Inc.; Centogene AG; Connective Tissue Gene Test LLC, a subsidiary of Health Network Laboratories, L.P.; Cooper Surgical, Inc.; Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Foundation Medicine, a subsidiary of Roche Holding AG; Fulgent Genetics, Inc., GeneDx, a subsidiary of OPKO Health, Inc.; Guardant Health, Inc.; Integrated Genetics, Sequenom Inc., Correlagen Diagnostics, Inc., and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings; Myriad Genetics, Inc.; Natera, Inc.; Perkin Elmer, Inc.; PreventionGenetics, LLC; Progenity, Inc.; and Sema4 Genomics;
- a few large, established general testing companies with large market share and significant channel power, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated;
- a large number of clinical laboratories in an academic or healthcare provider setting that perform clinical genetic testing on behalf of their affiliated institutions and often sell and market more broadly; and

- a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness including Illumina, Inc., which is also one of our suppliers.

Hospitals, academic medical centers and eventually physician practice groups and individual clinicians may also seek to perform at their own facilities the type of genetic testing we would otherwise perform for them. In this regard, continued development of equipment, reagents, and other materials as well as databases and interpretation services may enable broader direct participation in genetic testing and analysis.

Participants in closely related markets such as clinical trial or companion diagnostic testing could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide such potential competitors with significant advantages.

In addition, the biotechnology and genetic testing fields are intensely competitive both in terms of service and price, and continue to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

We also face competition as a result of our recently completed acquisition of ArcherDX. In particular, ArcherDX competes with numerous companies in the life sciences research, clinical diagnostics and drug development spaces, including, among others, Natera, QIAGEN N.V., Guardant Health, Inc., Thermo Fisher, Inc., Foundation Medicine, Caris Life Sciences, Inc., Tempus, Laboratory Corporation of America, Quest Diagnostics, Inc., NeoGenomics, Inc., BioReference Laboratories, Inc. and Illumina, Inc.

We believe the principal competitive factors in our market are:

- breadth and depth of content;
- quality;
- reliability;
- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;
- convenience of testing;
- brand recognition of test provider;
- additional value-added services and informatics tools;
- client service; and
- quality of website content.

Many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, higher margins on their tests, substantially greater financial, technological and research and development resources, selling and marketing capabilities, lobbying efforts, and more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do, sell their tests at prices designed to win significant levels of market share, or obtain reimbursement from more third-party payers and at higher prices than we do. We may not be able to compete effectively against these organizations. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payers are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies as use of next generation sequencing for clinical diagnosis and preventative care increases. Certain of our competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to website and systems development than we can. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. In addition, some of our competitors have obtained approval or clearance for certain of their tests from the U.S. Food and Drug Administration, or FDA. If payers decide to reimburse only for tests that are FDA-approved or FDA-cleared, or if they are more likely to reimburse for such tests, we may not be able to compete effectively unless we obtain similar approval or clearance for our tests. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.

Our expected future growth could create a strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as it grows. We may need to continue expanding our sales force to facilitate our growth, and we may have difficulties locating, recruiting, training and retaining sales personnel. Our ability to manage our growth effectively will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. As we grow, any failure of our controls or interruption of our production facilities or systems could have a negative impact on our business and financial operations. We plan to implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain, and failure to complete these activities in a timely and efficient manner could adversely affect our operations. Future growth in our business could also make it difficult for us to maintain our corporate culture. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including protected health information, or PHI, personally identifiable information, genetic information, credit card information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive patient data through our various customer tools and platforms. In addition to storing and transmitting sensitive data that is subject to multiple legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take what we believe to be reasonable and appropriate measures, including a formal, dedicated enterprise security program, to protect sensitive information from various compromises (including unauthorized access, disclosure, or modification or lack of availability), our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. For example, ArcherDX has been subject to phishing incidents and we may experience additional incidents in the future. Any such breach or interruption could compromise our networks and the information stored therein could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen.

Further, our various customer tools and platforms are currently accessible through our online portal and/or through our mobile applications, and there is no guarantee we can protect our them from a security breach. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business.

In addition to data security risks, we also face privacy risks. Should we actually violate, or be perceived to have violated, any privacy promises we make to patients or consumers, we could be subject to a complaint from an affected individual or interested privacy regulator, such as the FTC, a state Attorney General, an EU Member State Data Protection Authority, or a data protection authority in another international jurisdiction. This risk is heightened given the sensitivity of the data we collect.

Any security compromise that causes an apparent privacy violation could also result in legal claims or proceedings; liability under federal, state, foreign, or multinational laws that regulate the privacy, security, or breach of personal information, such as but not limited to the HIPAA, HITECH, state data security and data breach notification laws, the European Union's General Data Protection Regulation, or GDPR, the UK Data Protection Act of 2018; and related regulatory penalties. Penalties for failure to comply with a requirement of HIPAA or HITECH vary significantly, and, depending on the knowledge and culpability of the HIPAA-regulated entity, may include civil monetary penalties of up to \$1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to \$50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Penalties for unfair or deceptive acts or practices under the FTC Act or state Unfair and Deceptive Acts and Practices, or UDAP, statutes may also vary significantly.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. The GDPR took effect on May 25, 2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. The GDPR imposes strict requirements on controllers and processors of personal data, including enhanced protections for “special categories” of personal data, which includes sensitive information such as health and genetic information of data subjects. The GDPR also grants individuals various rights in relation to their personal data, including the rights of access, rectification, objection to certain processing and deletion. The GDPR provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, may result in significant administrative fines issued by EU regulators. Maximum penalties for violations of the GDPR are capped at 20M euros or 4% of an organization’s annual global revenue, whichever is greater.

Further, the United Kingdom’s decision to leave the European Union, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is still unclear whether the transfer of personal information from the EU to the United Kingdom will in the future remain lawful under the GDPR. The United Kingdom-EU post-Brexit trade deal provides that transfers of personal information to the United Kingdom will not be treated as restricted transfers to a non-EU country for a period of up to six months from January 1, 2021. However, unless the EU Commission makes an “adequacy finding” with respect to the United Kingdom before the end of that transition period, from that date the United Kingdom will be a “third country” under the GDPR and transfers of personal information from the EU to the United Kingdom will require an “adequacy mechanism,” such as the SCCs.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 28, 2018, California adopted the CCPA. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of consumers who reside in California. Among other things, the CCPA confers to California consumers the right to receive notice of the categories of personal information that will be collected by a business, how the business will use and share the personal information, and the third parties who will receive the personal information; the CCPA also confers rights to access, delete, or transfer personal information; and the right to receive equal service and pricing from a business after exercising a consumer right granted by the CCPA. In addition, the CCPA allows California consumers the right to opt out of the “sale” of their personal information, which the CCPA defines broadly as any disclosure of personal information to a third party in exchange for monetary or other valuable consideration. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure. California amended the law in September 2018 to exempt all PHI collected by certain parties subject to HIPAA, and further amended the law in September 2020 to clarify that de-identified data as defined under HIPAA will also be exempt from the CCPA. The California Attorney General’s final regulations implementing the CCPA took effect on August 14, 2020. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches resulting from a business’s failure to implement and maintain reasonable data security procedures that is expected to increase data breach litigation.

In addition, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, that is scheduled to go into effect on January 1, 2023. The CPRA would, among other things, amend the CCPA to give California residents the ability to limit the use of their sensitive information, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law. Other jurisdictions in the United States are beginning to propose laws similar to the CCPA. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business, results of operations, and financial condition.

It is possible the GDPR, CCPA and other emerging United States and international data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy laws and regulations may differ from country to country and state to state, and our obligations under these laws and regulations vary based on the nature of our activities in the particular jurisdiction, such as whether we collect samples from individuals in the local jurisdiction, perform testing in the local jurisdiction, or process personal information regarding employees or other individuals in the local jurisdiction. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We can provide no assurance that we are or will remain in compliance with diverse privacy and data security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and data security requirements could result in a variety of consequences, including civil or criminal penalties, litigation, or damage to our reputation, any of which could have a material adverse effect on our business.

We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.

Our performance, including our research and development programs and laboratory operations, largely depend on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization, including software developers, geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel to process and interpret our genetic tests. In addition, we may need to continue to expand our sales force with qualified and experienced personnel. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to scale our business, support our research and development efforts and our clinical laboratory. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

We need to scale our infrastructure in advance of demand for our tests, and our failure to generate sufficient demand for our tests would have a negative impact on our business and our ability to attain profitability.

Our success depends in large part on our ability to extend our market position, to provide customers with high-quality test reports quickly and at a lower price than our competitors, and to achieve sufficient test volume to realize economies of scale. In order to execute our business model, we intend to continue to invest heavily in order to significantly scale our infrastructure, including our testing capacity and information systems, expand our commercial operations, customer service, billing and systems processes and enhance our internal quality assurance program. We expect that much of this growth will be in advance of demand for our tests. Our current and future expense levels are to a large extent fixed and are largely based on our investment plans and our estimates of future revenue. Because the timing and amount of revenue from our tests is difficult to forecast, when revenue does not meet our expectations, we may not be able to adjust our spending promptly or reduce our spending to levels commensurate with our revenue. Even if we are able to successfully scale our infrastructure and operations, we cannot assure you that demand for our tests will increase at levels consistent with the growth of our infrastructure. If we fail to generate demand commensurate with this growth or if we fail to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition and results of operations could be adversely affected.

If we are not able to continue to generate substantial demand of our tests, our commercial success will be negatively affected.

Our business model assumes that we will be able to generate significant test volume, and we may not succeed in continuing to drive adoption of our tests to achieve sufficient volumes. Inasmuch as detailed genetic data from broad-based testing panels such as our tests have only recently become available at relatively affordable prices, the continued pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes. Given the substantial amount of additional information available from a broad-based testing panel such as ours, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate further demand for our tests, we will need to continue to make clinicians aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. A lack of or delay in clinical acceptance of broad-based panels such as our tests would negatively impact sales and market acceptance of our tests and limit our revenue growth and potential profitability. Genetic testing is expensive and many potential customers may be sensitive to pricing. In addition, potential customers may not adopt our tests if adequate reimbursement is not available, or if we are not able to maintain low prices relative to our competitors. Also, we may not be successful in increasing demand for our tests through our direct channel, in which we facilitate the ordering of our genetic tests by consumers through an online network of physicians.

If we are not able to generate demand for our tests at sufficient volume, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition and results of operations could be materially harmed.

We have devoted a portion of our resources to the development and commercialization of STRATAFIDE, and to research and development activities related to our PCM product for cancer monitoring, including clinical and regulatory initiatives to obtain diagnostic clearance and marketing approval. The demand for these regulated products is unproven, and we may not be successful in achieving market awareness and demand for these products through our sales and marketing operations.

If ArcherDX's products and services do not perform as expected, we may not realize the expected benefits of our recent acquisition of ArcherDX.

The success of ArcherDX's products depends on the market's confidence that it can provide reliable products that enable high quality diagnostic testing with high sensitivity and specificity and short turnaround times. There is no guarantee that the accuracy and reproducibility ArcherDX has demonstrated to date will continue as its product deliveries increase and its product portfolio expands.

ArcherDX's products and services use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. An operational, technological or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than ArcherDX anticipates or result in longer than expected turnaround times. In addition, labs are required to validate their processes before using ArcherDX products for clinical purposes. These validations are outside of our control. If our products do not perform, or are perceived to not have performed, as expected or favorably to competitive products, our consolidated operating results, reputation, and business will suffer, and ArcherDX may also be subject to legal claims arising from product limitations, errors, or inaccuracies.

In addition, we plan to match our test reports for STRATAFIDE to identified mutations with FDA-approved targeted therapies or relevant clinical trials of targeted therapies. If a patient or physician who orders a test using one of our products is unable to obtain, or be reimbursed for the use of, targeted therapies because they are not indicated in the FDA-approved label for treatment, the patient is unable to enroll in an identified clinical trial due to the enrollment criteria of the trial, or some other reason, the ordering physician may conclude the test report does not contain actionable information. If physicians do not believe our products consistently generate actionable information about their patients' disease or condition, they may be less likely to use our products.

Furthermore, we cannot provide assurance that customers will always use these products in the manner in which intended. Any intentional or unintentional misuse of these products by customers could lead to substantial civil and criminal monetary and non-monetary penalties, and could result in significant legal and investigatory fees.

The future growth of our distributed products business is partially dependent upon regulatory approval and market acceptance of our IVD products, including STRATAFIDE and PCM.

We anticipate that the future success of our distributed products business will depend in large part on our ability to effectively introduce enhanced or new offerings of IVD products, such as STRATAFIDE. The development and launch of enhanced or new products and services, whether research use only, or RUO, or IVD, require the completion of certain clinical development and commercialization activities that are complex, costly, time-intensive and uncertain, and require us to accurately anticipate patients', providers' and, if applicable, payers' attitudes and needs and emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that ArcherDX will not achieve its goals on a timely basis, or at all.

We have limited experience commercializing IVD products. We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new products or new services and result in increased costs and the diversion of management's attention and resources from other business matters.

An important factor in our ability to commercialize our distributed products is collecting data that supports their value proposition. The data collected from any studies we complete may not be favorable or consistent with its existing data or may not be statistically significant or compelling to the medical community or to third-party payers seeking such data for purposes of determining coverage for these products. This is particularly true with respect to service defects and errors. Any of the foregoing could have a negative impact on our ability to commercialize our future products, which could have a material adverse effect on our ability to realize the intended benefits of our recent acquisition of ArcherDX.

Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.

Our success depends on our ability to provide reliable, high-quality tests that incorporate rapidly evolving information about the role of genes and gene variants in disease and clinically relevant outcomes associated with those variants. Errors, such as failure to detect genomic variants with high accuracy, or mistakes, such as failure to identify, or incompletely or incorrectly identifying, gene variants or their significance, could have a significant adverse impact on our business.

Hundreds of genes can be implicated in some disorders, and overlapping networks of genes and symptoms can be implicated in multiple conditions. As a result, a substantial amount of judgment is required in order to interpret testing results for an individual patient and to develop an appropriate patient report. We classify variants in accordance with published guidelines as benign, likely benign, variants of uncertain significance, likely pathogenic or pathogenic, and these guidelines are subject to change. In addition, it is our practice to offer support to clinicians and geneticists ordering our tests regarding which genes or panels to order as well as interpretation of genetic variants. We also rely on clinicians to interpret what we report and to incorporate specific information about an individual patient into the physician's treatment decision.

The marketing, sale and use of our genetic tests could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on, information we provide to clinicians, geneticists or patients, and lead to claims against us if someone were to allege that a test failed to perform as it was designed, if we failed to correctly interpret the test results, if we failed to update the test results due to a reclassification of the variants according to new published guidelines, or if the ordering physician were to misinterpret test results or improperly rely on them when making a clinical decision. In addition, our entry into the reproductive health and pharmacogenetic testing markets expose us to increased liability. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain liability insurance, including for errors and omissions, we cannot assure you that such insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests. The occurrence of any of these events could have an adverse effect on our reputation and results of operations.

Our industry is subject to rapidly changing technology and new and increasing amounts of scientific data related to genes and genetic variants and their role in disease. Our failure to develop tests to keep pace with these changes could make us obsolete.

In recent years, there have been numerous advances in methods used to analyze very large amounts of genomic information and the role of genetics and gene variants in disease and treatment therapies. Our industry has and will continue to be characterized by rapid technological change, increasingly larger amounts of data, frequent new testing service introductions and evolving industry standards, all of which could make our tests obsolete. Our future success will also depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. Our tests could become obsolete and our business adversely affected unless we continually update our offerings to reflect new scientific knowledge about genes and genetic variations and their role in diseases and treatment therapies.

Our success will depend in part on our ability to generate sales using our internal sales team and through alternative marketing strategies.

We may not be able to market or sell our current tests and any future tests we may develop or acquire effectively enough to drive demand sufficient to support our planned growth. We currently sell our tests primarily through our internal sales force. Historically, our sales efforts have been focused primarily on hereditary cancer and more recently on reproductive health. Our efforts to sell our tests to clinicians and patients outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. In addition, following the acquisition of ArcherDX, our sales efforts have expanded to include distributed products sold to laboratories. In the past, we have increased our sales force each year in order to drive our growth, and in October 2020, we increased our sales force through the acquisition of ArcherDX. In addition to the efforts of our sales force, future sales will depend in large part on our ability to develop and substantially expand awareness of our company and our tests through alternative strategies including through education of key opinion leaders, through social media-related and online outreach, education and marketing efforts, and through focused channel partner strategies designed to drive demand for our tests. We also plan to continue to spend on consumer advertising in connection with our direct channel to consumers, which could be costly. We have limited experience implementing these types of marketing efforts. We may not be able to drive sufficient levels of revenue using these sales and marketing methods and strategies necessary to support our planned growth, and our failure to do so could limit our revenue and potential profitability.

We also use a limited number of distributors to assist internationally with sales, logistics, education and customer support. Sales practices utilized by our distributors that are locally acceptable may not comply with sales practices standards required under U.S. laws that apply to us, which could create additional compliance risk. If our sales and marketing efforts are not successful outside the United States, we may not achieve significant market acceptance for our tests outside the United States, which could adversely impact our business.

Impairment in the value of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.

We record goodwill and intangible assets at fair value upon the acquisition of a business. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired. Goodwill and indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of a reporting unit could result in an impairment of goodwill or intangible assets and, in turn, a charge to net income. Any such charges could have a material adverse effect on our results of operations or financial condition.

We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments, materials and services, and we may not be able to find replacements or immediately transition to alternative suppliers.

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Illumina, Inc., Integrated DNA Technologies Incorporated, Qiagen N.V., Roche Holdings Ltd. and Twist Bioscience Corporation for certain laboratory substances used in the chemical reactions incorporated into our processes, which we refer to as reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We do not have short- or long-term agreements with most of our suppliers, and our suppliers could cease supplying these materials and equipment at any time, or fail to provide us with sufficient quantities of materials or materials that meet our specifications. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations could impact our supply chain and laboratory operations as well as our ability to conduct our tests, and it could take a substantial amount of time to integrate replacement equipment into our laboratory operations.

We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot assure you that we will be able to secure alternative equipment, reagents and other materials, and bring such equipment, reagents and materials on line and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, we cannot assure you that replacement sequencers and associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business, financial condition, results of operations and reputation could be adversely affected.

Our planned STRATAFIDE and PCM products are currently being developed to use only Illumina's sequencing platform. Without access to these sequencers, we would be unable commercialize these products. In addition, any efforts to validate these distributed products on additional sequencing platforms would require significant resources, expenditures and time and attention of our management, and there is no guarantee that we will be successful in implementing any such sequencing platforms in a commercially sustainable way. We also cannot guarantee that it will appropriately prioritize or select alternative sequencing platforms on which to focus our efforts.

If our laboratories become inoperable due to disasters, health epidemics or for any other reasons, we will be unable to perform our tests and our business will be harmed.

We perform all of our tests at our production facilities in San Francisco and Irvine, California, in Golden, Colorado and in Seattle, Washington. Our laboratories and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use. Our laboratories may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding, fire and power outages, or by health epidemics, such as the COVID-19 pandemic, which may render it difficult or impossible for us to perform our tests for some period of time. This risk of natural disaster is especially high for us since we perform the substantial majority of our tests at our San Francisco laboratory, which is located in an active seismic region, and we do not have a redundant facility to perform the same tests in the event our San Francisco laboratory is inoperable. The inability to perform our tests or the backlog that could develop if our laboratories are inoperable for even a short period of time may result in the loss of customers or harm our reputation. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

ArcherDX relies on third-party laboratories to perform portions of its service offerings.

A large portion of ArcherDX's biopharmaceutical testing services is performed by third-party laboratories while the remaining portion is performed by third-party laboratories certified under the CLIA, or our CLIA-certified laboratory in Colorado. The third-party laboratories are subject to contractual obligations to perform these services for us, but are not otherwise under our control. We therefore do not control the capacity and quality control efforts of these third-party laboratories other than through our ability to enforce contractual obligations on volume and quality systems, and have no control over such laboratories' compliance with applicable legal and regulatory requirements. We also have no control over the timeliness of such laboratories' performance of their obligations to us, and the third-party laboratories that we have contracted with have in the past had, and occasionally continue to have, issues with delivering results to us or resolving issues with us within the time frames we expected or established in our contracts with them, which sometimes results in longer than expected turnaround times for, or negatively impacts the performance of, these tests and services. In the event of any adverse developments with these third-party laboratories or their ability to perform their obligations in a timely manner and in accordance with the standards that we and our customers expect, our ability to service customers may be delayed, interrupted or otherwise adversely affected, which could result in a loss of customers and harm to our reputation. Furthermore, when these issues arise, we have had to expend time, management's attention and other resources to address and remedy such issues.

We may not have sufficient alternative backup if one or more of the third-party laboratories that we contract with are unable to satisfy their obligations to us with sufficient performance, quality and timeliness. Any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at one or more of these third-party laboratories' facilities that causes a loss of capacity would heighten the risks that we face. Changes to or termination of agreements or inability to renew agreements with these third-party laboratories or enter into new agreements with other laboratories that are able to perform such portions of our service offerings could impair, delay or suspend our efforts to market and sell these services.

The loss of any member or change in structure of our senior management team could adversely affect our business.

Our success depends in large part upon the skills, experience and performance of members of our executive management team and others in key leadership positions. The efforts of these persons will be critical to us as we continue to develop our technologies and test processes and focus on scaling our business. If we were to lose one or more key executives, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. All of our executives and employees are at-will, which means that either we or the executive or employee may terminate their employment at any time. We do not carry key person insurance for any of our executives or employees. In addition, we do not have a long-term retention agreement in place with our president and chief executive officer.

Development of new tests is a complex process, and we may be unable to commercialize new tests on a timely basis, or at all.

We cannot assure you that we will be able to develop and commercialize new tests on a timely basis. Before we can commercialize any new tests, we will need to expend significant funds in order to:

- conduct research and development;
- further develop and scale our laboratory processes; and
- further develop and scale our infrastructure to be able to analyze increasingly larger and more diverse amounts of data.

Our testing service development process involves risk, and development efforts may fail for many reasons, including:

- failure of any test to perform as expected;
- lack of validation or reference data; or
- failure to demonstrate utility of a test.

As we develop tests, we will have to make significant investments in development, marketing and selling resources. In addition, competitors may develop and commercialize competing tests faster than we are able to do so.

Our research and development efforts to add additional indications to our IVD products, if approved, will be hindered if we are not able to contract with third parties for access to tissue samples.

Under standard clinical practice, tumor biopsies removed from patients are preserved and stored in formalin-fixed paraffin embedded, or FFPE, format, and liquid biopsies are taken with a blood draw and stored in blood collection tubes. In order to add additional indications to our IVD products, if approved, we will need to secure access to these FFPE tumor biopsy and liquid biopsy samples, as well as information pertaining to the clinical outcomes of the patients from which they were derived for its IVD development activities. Others compete with us for access to these samples. Additionally, the process of negotiating access to samples is lengthy because it typically involves numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters. If we are unable to negotiate access to tissue samples on a timely basis or on commercially reasonable terms, or at all, or if other laboratories or competitors secure access to these samples before us, our ability to research, develop and commercialize future IVD products will be limited or delayed.

We depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process and drug metabolism, our clinical report optimization systems, our customer-facing web-based software, our customer reporting, and our various customer tools and platforms. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, customer relationship management, regulatory compliance and other infrastructure operations. In addition, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design, and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, and general administrative activities, including financial reporting.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to clinicians, billing payers, processing reimbursement appeals, handling physician or patient inquiries, conducting research and development activities, and managing the administrative and financial aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and results of operations.

Technical problems have arisen, and may arise in the future, in connection with our data and systems, including those that are hosted by third-party providers, which have in the past and may in the future result in interruptions in our business and operations. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests.

Genetic testing has raised ethical, legal and social issues regarding privacy rights and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genomic tests even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests, either of which could have an adverse effect on our business, financial condition or results of operations.

Our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- logistics and regulations associated with shipping samples, including infrastructure conditions, customs and transportation delays;
- limits on our ability to penetrate international markets if we do not to conduct our tests locally;
- natural disasters, including the recent and ongoing outbreak and spreading of Coronavirus, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our international operations and, consequently, our revenue and results of operations.

In addition, applicable export or import laws and regulations such as prohibitions on the export of samples imposed by countries outside of the United States, or international privacy or data restrictions that are different or more stringent than those of the United States, may require that we build additional laboratories or engage in joint ventures or other business partnerships in order to offer our tests internationally in the future. Any such restrictions would impair our ability to offer our tests in such countries and could have an adverse effect on our business, financial condition and results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

At December 31, 2020, our total gross deferred tax assets were \$418.9 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, our net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets are primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Some of our prior acquisitions have resulted in an ownership change, and we may experience ownership changes in the future. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, or other future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. In addition, the Tax Cuts and Jobs Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Also, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks related to government regulation

If the FDA regulates the tests we currently offer as LDTs as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.

We provide many of our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by CLIA, and state law, respectively).

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency’s requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled “Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)” and “FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs),” respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. Subsequently, on January 13, 2017, the FDA published a “discussion paper” in which it outlined a substantially revised “possible approach” to the oversight of LDTs.

In March 2020, a bill titled the “Verifying Accurate Leading-edge IVCT Development Act of 2020,” or VALID Act, was officially introduced in Congress. The bill proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test, or IVCT, category of regulated products, which includes LDTs, and a regulatory structure under the FDA. As proposed, the bill grandfathers many existing tests from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (e.g., registration and listing, adverse event reporting). Later that month, Senator Paul introduced the Verified Innovative Testing in American Laboratories Act of 2020, or VITAL Act, which proposes that all aspects of “laboratory-developed testing procedures” be subject to regulation under CLIA, and that no aspects of such procedures be subject to regulation by the FDA. We cannot predict if either of these bills will be enacted in their current (or any other) form and cannot quantify the effect of these bills on our business.

In August 2020, the U.S. Department of Health and Human Services, the parent agency for FDA, announced that the FDA “will not require premarket review of LDTs absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances.” It is unclear at this time whether this policy will be retained by the Biden Administration, and if so, when the FDA might seek to begin the notice and comment rulemaking process.

Legislative proposals addressing the FDA’s oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals may be introduced from time-to-time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA’s plans to regulate certain LDTs as medical devices is difficult to predict at this time.

In April 2020, we completed our acquisition of Genelex Solutions, LLC, which offers certain pharmacogenetic, or PGx, tests as LDTs. Recently the FDA has taken a more active role in the oversight of PGx tests offered as LDTs. In 2019, the FDA contacted several clinical laboratories, including Genelex, to demand changes to PGx test reports and marketing materials. In February 2020, the FDA issued a statement indicating that it continues to have concerns about the claims that certain clinical laboratories make with respect to their PGx tests, and published tables that list PGx associations for which FDA has determined that the data support therapeutic management recommendations, a potential impact on safety or response, or a potential impact on pharmacokinetic properties only, respectively. To date, however, the FDA has not provided any general guidance on the type(s) of claims or other characteristics that will cause a PGx test to fall outside FDA's enforcement discretion. As such, the extent to which the FDA will allow any laboratory, including Genelex or Invitae, to offer PGx tests in their current form without meeting FDA regulatory requirements for medical devices is unclear at this time.

If the FDA ultimately regulates certain LDTs (either as medical devices or as part of a new stand-alone regulatory category for IVCTs), whether via individualized enforcement action, or more generally, as outlined in final guidance or final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition and results of operations.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

In addition, in November 2013, the FDA issued final guidance regarding the distribution of products labeled for research use only. Certain of the reagents and other products we use in our tests are labeled as research use only products. Certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

If we fail to comply with federal, state and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers, for our tests. We have current CLIA certifications to conduct our tests at our laboratories in San Francisco and Irvine, California, Golden, Colorado, and Seattle, Washington. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories.

We are also required to maintain in-state licenses to conduct testing in California and Washington. California and Washington laws establish standards for day-to-day operation of our clinical reference laboratories in San Francisco and Irvine, and in Seattle, respectively, which include the training and skills required of personnel and quality control. (Our Colorado laboratory is not required to maintain a state clinical laboratory license.)

Several states require the licensure of out-of-state laboratories that accept specimens from those states. Our California laboratories hold the required out-of-state laboratory licenses for Maryland, New York, Pennsylvania, and Rhode Island. Our Washington laboratory holds the required out-of-state laboratory licenses in Maryland, New York, Pennsylvania, and Rhode Island (but not California). Our laboratory in Colorado holds the required out-of-state laboratory licenses for California, Maryland, Pennsylvania and Rhode Island (but not New York).

In addition to having laboratory licenses in New York, our clinical reference laboratories are approved on test-specific bases for the tests they run as LDTs by the New York State Department of Health, or NYDOH, for tests offered to patients in New York. Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of samples necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays.

In order to eventually market certain of our current or future products and services in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding quality, safety, performance and efficacy. In addition, clinical trials or clinical investigations conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory clearance, authorization or approval in one country does not guarantee regulatory clearance, authorization or approval in any other country. For example, the performance characteristics of certain of our products and services may need to be validated separately in specific ethnic and genetic populations. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory clearance, authorization or approval could result in difficulties and costs for us and our collaborators and require additional preclinical studies, clinical trials or clinical investigations which could be costly and time-consuming. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of certain of our products and services in those countries. The foreign regulatory clearance, authorization or approval process involves all of the risks and uncertainties associated with FDA clearance, authorization or approval. ArcherDX currently sells its RUO products outside the United States but has no experience in obtaining regulatory clearance, authorization or approval in international markets other than Japan. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products and services will be unrealized.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and cancellation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certifications, a state or foreign license, or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

The College of American Pathologists, or CAP, maintains a clinical laboratory accreditation program. CAP asserts that its program is "designed to go well beyond regulatory compliance" and helps laboratories achieve the highest standards of excellence to positively impact patient care. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. We have CAP accreditations for our laboratories. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

We may not be able to obtain regulatory clearance or approval of our IVD products, or even if approved, such products may not be approved for guideline inclusion, which could adversely our ability to realize the intended benefits of our recently completed acquisition of ArcherDX.

A significant portion of ArcherDX's commercial strategy, including for STRATAFIDE and PCM, relies on receiving regulatory approvals with guideline inclusion to strengthen its position in establishing coverage and reimbursement of its IVD products with both public and private payers. If we do not receive such regulatory approvals in a timely manner or at all, or we are not successful in obtaining such guideline inclusion, it may not be able to commercialize our IVD products. Additionally, third-party payers may be unwilling to provide sufficient coverage and reimbursement for these products necessary for hospitals and other healthcare providers to adopt our solutions as part of their oncological treatment strategy. ArcherDX has also focused its efforts on the development of PCM for FDA clearance and approval as a prognostic device for predicting recurrence of a primary cancer after initial treatment, which can include surgery alone or surgery plus adjuvant therapy.

Moreover, development of the data necessary to obtain regulatory clearance and/or approval of an IVD, such as STRATAFIDE, is time-consuming and carries with it the risk of not yielding the desired results. The performance achieved in published studies may not be repeated in later studies that may be required to obtain FDA clearance and/or approval or regulatory approvals in foreign jurisdictions. Limited results from earlier-stage verification studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over longer periods of time. Unfavorable results from ongoing preclinical and clinical studies could result in delays, modifications or abandonment of ongoing analytical or future clinical studies, or abandonment of a product development program, or may delay, limit or prevent regulatory approvals or clearances or commercialization of our product candidates, any of which may materially impact our ability to realize the expected benefits of our recently completed acquisition of ArcherDX.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- HIPAA, which establishes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions;
- amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators and expand vicarious liability, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- the GDPR, which imposes strict privacy and security requirements on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, including sensitive information such as health and genetic information of data subjects;
- the CCPA, which, among other things, regulates how subject businesses may collect, use, and disclose the personal information of consumers who reside in California, affords rights to consumers that they may exercise against businesses that collect their information, and requires implementation of reasonable security measures to safeguard personal information of California consumers;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or recommend purchasing, leasing or ordering, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;
- EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and reaches beyond federal health care programs, to include private insurance;
- the federal physician self-referral law, known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity unless an exception applies, and prohibits an entity from billing for designated health services furnished pursuant to a prohibited referral;

- the federal false claims law, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the HIPAA fraud and abuse provisions, which create new federal criminal statutes that prohibit, among other things, defrauding health care benefit programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;
- the 21st Century Cures Act information blocking prohibition, which prohibits covered actors from engaging in certain practices that are likely to interfere with the access, exchange, or use of electronic health information;
- the Physician Payments Sunshine Act and similar state laws that require reporting of certain payments and other transfers of value made by applicable manufacturers, directly or indirectly, to or on behalf of covered recipients including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- state laws that limit or prohibit the provision of certain payments and other transfers of value to certain covered healthcare providers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payers; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance may also be subject to governmental review. The growth of our business and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in Federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Healthcare policy changes, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition, results of operations and cash flows.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Policy changes or implementation of new health care legislation could result in significant changes to health care systems. In the United States, this could include potential modification or repeal of all or parts of the Affordable Care Act.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA (as amended by the Further Consolidated Appropriations Act, 2020 and the Coronavirus Aid, Relief, and Economic Security Act, respectively) and its implementing regulations, clinical laboratories must report to CMS private payer rates beginning in 2017, and then in 2022 and every three years thereafter for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests and every year for advanced diagnostic laboratory tests.

We do not believe that our tests meet the definition of advanced diagnostic laboratory tests, but in the event that we seek designation for one or more of our tests as an advanced diagnostic laboratory test and the tests are determined by CMS to meet these criteria or new criteria developed by CMS, we would be required to report private payer data for those tests annually. Otherwise, we will be required to report private payer rates for our tests on an every three years basis starting in 2022. Laboratories that fail to timely report the required payment information may be subject to substantial civil money penalties.

As set forth in the PAMA final rule, for tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are paid based upon these reported private payer rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the cross-walk or gap-fill methodology. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test. The payment rates calculated under PAMA went into effect starting January 1, 2018. Where applicable, reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020. Rates will be held at 2020 levels during 2021, and then, where applicable based upon median private payer rates reported in 2017 or 2022, reduced by up to 15% per test per year in each of 2022 through 2024 (with a second round of private payer rate reporting in 2022 to establish rates for 2023 through 2025).

PAMA also authorized the adoption of new, temporary billing codes and/or unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The CPT® Editorial Panel approved a proposal to create a new section of billing codes to facilitate implementation of this section of PAMA, but these codes would apply to our tests only if we apply for such codes.

In March 2018, CMS published a national coverage determination, or NCD, for next generation sequencing, or NGS tests for somatic (acquired) cancer testing. CMS subsequently updated this NCD in January 2020 to address coverage for NGS tests for germline (inherited) cancer testing and to clarify certain aspects of Medicare's coverage of NGS for somatic cancer testing. For somatic cancer testing, the updated NCD establishes full coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays that report results using report templates that specify treatment options when offered for their FDA-approved or FDA-cleared use(s), ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer) who have not have previously been tested with the same test using NGS for the same cancer genetic content, and have decided to seek further cancer treatment (e.g., therapeutic chemotherapy). The NCD also gives MACs the authority to establish local coverage for NGS-based somatic cancer assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It appears that NGS-based somatic cancer tests provided for patients with cancer that do not meet the above-referenced criteria, e.g., patients with earlier stage cancers, are currently nationally non-covered under the NCD.

Effective January 27, 2020, the NCD also established full coverage for FDA-approved or FDA-cleared NGS-based germline tests that report results using report templates that specify treatment options when ordered by the patient's treating physician for patients with ovarian or breast cancer, a clinical indication for germline testing for hereditary breast or ovarian cancer, and a risk factor for germline breast or ovarian cancer, provided the patient has not previously been tested with the same germline test using NGS for the same germline genetic content. The NCD also gives MACs the authority to establish local coverage for NGS-based germline tests for ovarian or breast cancer that are not FDA-approved or FDA-cleared, as well as for NGS-based tests for any other cancer diagnosis (regardless of the test's FDA regulatory status) when offered to patients meeting the above-referenced criteria for germline testing. Since we already have local coverage for our germline tests for ovarian and breast cancer, we believe that the NCD will not have a material impact on which of our tests will be reimbursable by CMS for Medicare patients.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. For instance, the payment reductions imposed by the Affordable Care Act and the expansion of the federal and state governments' role in the U.S. healthcare industry as well as changes to the reimbursement amounts paid by payers for our tests and future tests or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Notably, Congress enacted legislation in 2017 that eliminated the Affordable Care Act's "individual mandate" beginning in 2019, which may significantly impact the number of covered lives participating in exchange plans. The U.S. Supreme Court is currently reviewing the constitutionality of the Affordable Care Act, although it is unclear when a decision will be made. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would increase our billing and collecting costs and decrease our revenue. Further, it is possible that additional governmental action be taken in response to the COVID-19 pandemic.

If we use hazardous materials in a manner that causes injury, we could be liable for resulting damages.

Our activities currently require the use of hazardous chemicals and biological material. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. In 2018, we decommissioned our laboratory in Massachusetts; however, we could be held liable for any damages resulting from our prior use of hazardous chemicals and biological materials at this facility. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

We could be adversely affected by violations of the FCPA and other worldwide anti-bribery laws.

We are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are increasing our direct sales and operations personnel outside the United States, in which we have limited experience. We use a limited number of independent distributors to sell our tests internationally, which requires a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

Risks related to our intellectual property

One of ArcherDX's competitors has alleged that its Anchored Multiplex PCR, or AMP, chemistry and products using AMP are infringing on its intellectual property, and ArcherDX may be required to redesign the technology, obtain a license, cease using the AMP chemistry altogether and/or pay significant damages, among other consequences, any of which would have a material adverse effect on ArcherDX's business as well as our financial condition and results of operations, and the intended benefits of our recently completed acquisition of ArcherDX.

ArcherDX's AMP chemistry underlies all of its RUO products and is also the foundation of STRATAFIDE and Personalized Cancer Monitoring, or PCM. On January 27, 2020, one of ArcherDX's competitors, Natera, Inc., or Natera, filed a complaint against ArcherDX in the United States District Court for the District of Delaware, alleging that ArcherDX's products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814. On April 15, 2020, Natera amended its complaint to allege that ArcherDX's products using AMP chemistry and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, U.S. Patent No. 10,590,482, and U.S. Patent No. 10,597,708, each of which are held by Natera. On August 6, 2020, Natera filed another complaint against ArcherDX in the United States District Court for the District of Delaware alleging that ArcherDX's products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,731,220 (together with U.S. Patent Nos. 10,538,814, 10,557,172, 10,590,482, and 10,597,708, the "Natera Asserted Patents.") Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of The Natera Asserted Patents. On October 13, 2020, the court issued an order denying ArcherDX's motion for dismissal of Natera's infringement claims against STRATAFIDE, PCM, and ArcherMET, and declined to enter judgment that U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On January 12, 2021, the court issued an order granting Natera leave to amend its complaint to add Invitae as a co-defendant and plead allegations that ArcherDX and Invitae induce end-users to infringe the patents-in-suit. Natera filed its Second Amended Complaint on the same day and served Invitae on January 15, 2021. The litigations have now been consolidated for all purposes, are ongoing, and trial has been scheduled for May 2022.

If any of ArcherDX's products or ArcherDX's use of AMP chemistry is found to infringe any of the Natera Asserted Patents, it could be required to redesign its technology or obtain a license from Natera to continue developing, manufacturing, marketing, selling and commercializing AMP and its products. However, ArcherDX may not be successful in the redesign of its technology or able to obtain any such license on commercially reasonable terms or at all. Even if ArcherDX were able to obtain a license, it could be non-exclusive, thereby giving Natera and other third parties the right to use the same technologies licensed to ArcherDX, and it could require ArcherDX to make substantial licensing, royalty and other payments. ArcherDX also could be forced, including by court order, to permanently cease developing, manufacturing, marketing and commercializing ArcherDX's products that are found to be infringing. In addition, ArcherDX could be found liable for significant monetary damages, including treble damages and attorneys' fees, if ArcherDX is found to have willfully infringed any of the Natera Asserted Patents. Even if ArcherDX were ultimately to prevail, litigation with Natera could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We cannot reasonably estimate the final outcome, including any potential liability or any range of potential future charges associated with these litigations. However, any finding of infringement by ArcherDX of any of the Natera Asserted Patents could have a material adverse effect on the business of ArcherDX and the benefits we expected to achieve through our acquisition of ArcherDX, as well as our financial condition and results of operations.

Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation will require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price.

Our commercial success will depend in part on our avoiding infringement of patents and proprietary rights of third parties, including for example the intellectual property rights of competitors. As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests, and enter new markets, competitors might claim that our tests infringe or misappropriate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. Our activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. For example, as discussed in the preceding risk factor, we are currently engaged in litigation with a competitor of ArcherDX alleging infringement. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We may be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, regardless of merit, could cause us to incur substantial expenses and be a substantial diversion of our employee resources. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our business and stock price. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, possibly including treble damages and attorneys' fees if we are found to have willfully infringed patents; (2) obtain one or more licenses, which may not be available on commercially reasonable terms (if at all); (3) pay royalties; and/or (4) redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, all of which could have a material adverse impact on our cash position and business and financial condition.

If licenses to third-party intellectual property rights are or become required for us to engage in our business, we may be unable to obtain them at a reasonable cost, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in the introduction of tests while we attempt to develop alternatives. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing tests, which could materially affect our ability to grow and thus adversely affect our business and financial condition.

Developments in patent law could have a negative impact on our business.

Although we view current U.S. Supreme Court precedent to be aligned with our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts (such as patient genetic data) and an understanding of that fact's implications (such as a patient's risk of disease associated with certain genetic variations) should not be patentable, it is possible that subsequent determinations by the U.S. Supreme Court or other federal courts could limit, alter or potentially overrule current law. Moreover, from time to time the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office, or USPTO, may change the standards of patentability, and any such changes could run contrary to, or otherwise be inconsistent with, our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts and an understanding of that fact's implications should not be patentable, which could result in third parties newly claiming that our business practices infringe patents drawn from categories of patents which we currently view to be invalid as directed to unpatentable subject matter. For example, the U.S. Senate Judiciary Committee, Subcommittee on Intellectual Property held hearings in 2019 regarding a legislative proposal that would overrule current U.S. Supreme Court precedent concerning the scope of patentable subject matter. Our President and Chief Executive Officer, Sean George, appeared before this subcommittee. If such proposal were to be formulated as a bill and enacted into law, there could be an increase in third-party claims to patent rights over correlations between patient genetic data and its interpretation and such third parties may assert that our business practices infringe some of those resulting patent rights.

Our inability to effectively protect our proprietary technologies, including the confidentiality of our trade secrets, could harm our competitive position.

We currently rely upon trade secret protection and copyright, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, and to a limited extent patent protection, to protect our confidential and proprietary information. Although our competitors have utilized and are expected to continue utilizing similar methods and have aggregated and are expected to continue to aggregate similar databases of genetic testing information, our success will depend upon our ability to develop proprietary methods and databases and to defend any advantages afforded to us by such methods and databases relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our methods and databases and thereby erode any competitive advantages we may have.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. In this regard, we have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, we expect that potential patent coverage we may obtain will not be sufficient to prevent substantial competition. In this regard, we believe it is probable that others will independently develop similar or alternative technologies or design around those technologies for which we may obtain patent protection. In addition, any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. Questions as to inventorship or ownership may also arise. Any finding that our patents or applications are unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, which would be expensive, and, if we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel.

We expect to rely primarily upon trade secrets and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. Among other things, we seek to protect our trade secrets and confidential information by entering into confidentiality agreements with employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees and consultants will provide meaningful protection for our trade secrets and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Accordingly, there also can be no assurance that our trade secrets will not otherwise become known or be independently developed by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks related to being a public company

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and the New York Stock Exchange, or NYSE, impose a number of requirements on public companies, including with respect to corporate governance practices. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In addition, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, enacted in 2010, includes significant corporate governance and executive-compensation-related provisions. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. If these requirements divert the attention of our management and personnel from other aspects of our business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, these rules and regulations applicable to public companies substantially increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time consuming and costly. It may also be more expensive for us to obtain director and officer liability insurance.

If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

We are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have compiled the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We need to maintain and enhance these processes and controls as we grow and we have required, and may continue to require, additional personnel and resources to do so.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal controls, our management will be unable to conclude that our internal control over financial reporting is effective. Our independent registered public accounting firm is required to issue an attestation report on the effectiveness of our internal control over financial reporting every fiscal year. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in the restatement of our financial results in the future.

Risks related to our indebtedness

The terms of our credit agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In October 2020, we entered into a credit agreement with Perceptive Credit Holdings II, LP, pursuant to which we borrowed an aggregate principal amount of \$135.0 million, or the 2020 Term Loan. The 2020 Term Loan is secured by a first priority lien on all of our and our subsidiaries' assets (including our intellectual property) and is guaranteed by our subsidiaries, in each case, excluding certain excluded assets and immaterial subsidiaries. If the 2020 Term Loan is prepaid, we may be required to pay a prepayment fee of up to 6% and a make-whole fee, in each case depending on when the prepayment is made.

The credit agreement restricts our ability to pursue certain mergers, acquisitions, amalgamations or consolidations, other than permitted acquisitions, that we may believe to be in our best interest. In addition, the credit agreement contains financial covenants that require us to maintain a minimum cash balance and minimum quarterly revenue levels. If we default under the credit agreement, the lender will be able to declare all obligations immediately due and payable, including prepayment fees and other obligations. The lender could declare an event of default under the credit agreement upon the occurrence of any event that it interprets as a material adverse change or material adverse effect, each as defined under the credit agreement. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

In September 2019, we issued \$350.0 million aggregate principal amount of our Convertible Senior Notes in a private placement and in October 2020 we entered into our credit agreement and borrowed \$135.0 million through the 2020 Term Loan.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to settle conversions of the Convertible Senior Notes in cash or to repurchase the notes upon a fundamental change, and our current credit agreement contains and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the notes.

Holders of the notes have the right to require us to repurchase all or any portion of their notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the notes being converted. However, we only have limited ability to make those cash payments under our credit agreement and, even if the credit agreement limitations are no longer in effect, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of notes surrendered therefor or notes being converted. In addition, our ability to repurchase the notes or to pay cash upon conversions of the notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the notes as required by the indenture would constitute a default under the indenture. A default under the indenture or the occurrence of the fundamental change itself could also lead to a default under our credit agreement and any agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and to repay or repurchase the notes.

The conditional conversion feature of the Convertible Senior Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the notes is triggered, such as was the case for the quarter ending March 31, 2021, holders of notes will be entitled to convert the notes at any time during specified periods at their option. If one or more holders elect to convert their notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities that may be settled in cash, such as the notes, could have a material effect on our reported financial results.

In May 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement), which has subsequently been codified as Accounting Standards Codification 470-20, Debt with Conversion and Other Options, or ASC 470-20. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet at issuance, and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the notes. As a result, we are required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the notes to their face amount over the term of the notes. We will report larger net losses or lower net income in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's non-convertible coupon interest rate, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the notes.

In addition, under certain circumstances, convertible debt instruments (such as the notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the notes are not included in the calculation of diluted net income (loss) per share except to the extent that the conversion value of the notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. In August 2020, the FASB amended these accounting standards, effective for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020, to eliminate the treasury stock method for convertible instruments and instead require application of the "if-converted" method. Under that method, diluted net income (loss) per share would generally be calculated assuming that all the notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the "if-converted" method may reduce our reported diluted net income (or further increase our diluted net loss, as the case may be) per share.

General risk factors

Our stock price is volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

The trading price of our common stock is volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated fluctuations in our operating results;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

- issuance of new or updated research or reports by securities analysts or changed recommendations for our stock;
- our focus on long-term goals over short-term results;
- the level of short interest in our stock, and the effect of short sellers on the price of our stock;
- the timing and magnitude of our investments in the growth of our business;
- actual or anticipated changes in regulatory oversight of our business;
- additions or departures of key management or other personnel;
- disputes or other developments related to our intellectual property or other proprietary rights, including litigation;
- changes in reimbursement by current or potential payers;
- general economic and market conditions; and
- issuances of significant amounts of our common stock.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, including COVID-19, may seriously affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock, change their price targets, issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, the terms of our credit agreement restrict our ability to pay dividends. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 20,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our chairman of the board or our chief executive officer;

- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum; and
- require a super-majority of votes to amend certain of the above-mentioned provisions as well as to amend our bylaws generally.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law; or
- any action asserting a claim against us governed by the internal affairs doctrine.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of December 31, 2020, we had outstanding 185.9 million shares of our common stock, options to purchase 4.8 million shares of our common stock (of which 4.4 million were exercisable as of that date), outstanding restricted stock units, or RSUs, representing 6.6 million shares of our common stock (which includes an estimated number of RSUs, subject to certain employee's continued service with us, or Time-based RSUs, and RSUs that are performance based RSUs, or PRSUs, granted in connection with an acquisition), outstanding Series A convertible preferred stock convertible into 0.1 million shares of our common stock and warrants to purchase 0.2 million shares of our common stock. The foregoing does not include shares that may be issuable in connection with indemnification hold-backs and contingent consideration related to our acquisitions other than ArcherDX, and up to 22.0 million shares which may be issuable upon the achievement of certain milestones related to our acquisition of ArcherDX, inducement awards issued in connection with an acquisition, or shares that may be issuable in the future in connection with the convertible senior notes. Also not included are the shares issued or issuable in connection with acquisitions after December 31, 2020, including approximately 1.4 million shares of our common stock that we will register for resale following the filing of this Report. The sale or the availability for sale of a large number of shares of our common stock in the public market could cause the price of our common stock to decline.

ITEM 1B. Unresolved Staff Comments.

None.

ITEM 2. Properties.

Our headquarters and main production facility is located in San Francisco, California, where we currently lease and occupy approximately 103,000 square feet of laboratory and office space. The lease for this facility expires in July 2026 and we may renew the lease for an additional ten years.

We also lease approximately 330,000 square feet of additional office and laboratory space domestically in California, Colorado, Massachusetts, New York and Washington, and internationally in Australia and Israel.

We believe that our facilities are adequate for our current needs and that additional space will be available on commercially reasonable terms if required.

ITEM 3. Legal Proceedings.

For a discussion of legal matters as of December 31, 2020, see Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this report, which is incorporated into this item by reference.

ITEM 4. Mine Safety Disclosure.

Not applicable.

PART II

ITEM 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

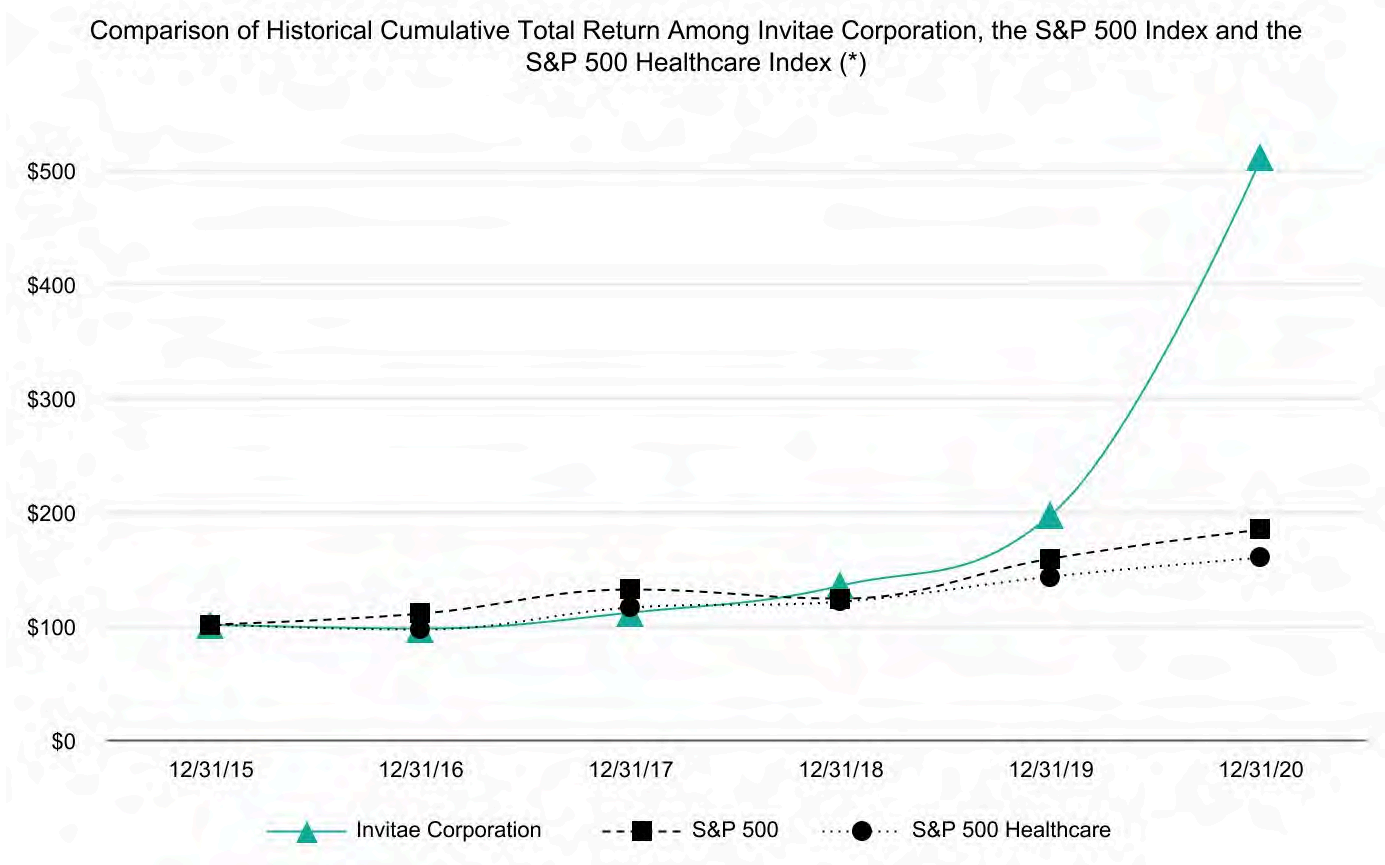
Our common stock has been publicly traded on the New York Stock Exchange under the symbol “NVTA” since February 12, 2015. Prior to that time, there was no public market for our common stock.

As of February 19, 2021, there were 247 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. In addition, the terms of the credit agreement restrict our ability to pay dividends. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements and general business conditions and other factors that our board of directors may deem relevant.

Stock performance graph

The following information shall not be deemed to be soliciting material or to be filed with the SEC, or subject to Regulations 14A or 14C under the Securities Exchange Act of 1934, or Exchange Act, or to the liabilities of Section 18 of the Exchange Act nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.



(*) The above graph shows the cumulative total stockholder return of an investment of \$100 in cash on December 31, 2015 through December 31, 2020 for: (i) our common stock; (ii) the S&P 500 Index; and (iii) the S&P 500 Healthcare Index. All values assume reinvestment of the full amount of all dividends. The comparisons in the table are not intended to be forecasts or indicative of future stockholder returns.

	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020
Invitae Corporation	\$ 100.00	\$ 96.71	\$ 110.60	\$ 134.71	\$ 196.47	\$ 509.26
S&P 500	\$ 100.00	\$ 109.54	\$ 130.81	\$ 122.65	\$ 158.07	\$ 183.77
S&P 500 Healthcare Index	\$ 100.00	\$ 95.64	\$ 114.77	\$ 120.16	\$ 142.60	\$ 158.90

ITEM 6. Selected Financial Data.

The information set forth below should be read together with “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited consolidated financial statements and related notes included elsewhere in this report. The selected consolidated balance sheet data at December 31, 2020 and 2019 and the selected consolidated statements of operations data for each of the years ended December 31, 2020, 2019, and 2018 have been derived from our audited consolidated financial statements that are included elsewhere in this report. The selected consolidated balance sheet data at December 31, 2018, 2017 and 2016 and the selected consolidated statement of operations data for the years ended December 31, 2017 and 2016 have been derived from our audited consolidated financial statements not included in this report. Historical results are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
	2020 ⁽¹⁾	2019 ⁽¹⁾	2018 ⁽³⁾	2017 ⁽¹⁾	2016
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Test revenue	\$ 272,310	\$ 212,473	\$ 144,560	\$ 65,169	\$ 24,840
Other revenue	7,288	4,351	3,139	3,052	208
Total revenue	279,598	216,824	147,699	68,221	25,048
Cost of revenue ⁽⁴⁾	198,275	118,103	80,105	50,142	27,878
Research and development ⁽⁴⁾	240,605	141,526	63,496	46,469	44,630
Selling and marketing ⁽⁴⁾	168,317	122,237	74,428	53,417	28,638
General and administrative ⁽⁴⁾	324,573	79,070	52,227	39,472	24,085
Loss from operations	(652,172)	(244,112)	(122,557)	(121,279)	(100,183)
Other income (expense), net	(32,332)	(3,891)	(2,568)	(303)	348
Interest expense	(29,766)	(12,412)	(7,030)	(3,654)	(421)
Net loss before taxes	(714,270)	(260,415)	(132,155)	(125,236)	(100,256)
Income tax benefit	(112,100)	(18,450)	(2,800)	(1,856)	—
Net loss	\$ (602,170)	\$ (241,965)	\$ (129,355)	\$ (123,380)	\$ (100,256)
Net loss per share, basic and diluted ⁽⁵⁾	\$ (4.47)	\$ (2.66)	\$ (1.94)	\$ (2.65)	\$ (3.02)
Shares used in computing net loss per share, basic and diluted	134,587	90,859	66,747	46,512	33,176

	As of December 31,				
	2020 ⁽¹⁾	2019 ^(1,2)	2018 ⁽³⁾	2017 ⁽¹⁾	2016
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 124,794	\$ 151,389	\$ 112,158	\$ 12,053	\$ 66,825
Marketable securities	229,186	240,436	13,727	52,607	25,798
Working capital	332,187	360,538	129,127	53,294	87,047
Total assets	3,430,485	781,601	282,959	211,078	130,651
Debt	104,449	—	74,477	39,084	12,102
Convertible senior notes, net	283,724	268,755	—	—	—
Total liabilities	1,454,192	401,961	121,120	89,284	31,577
Accumulated deficit	(1,360,847)	(758,677)	(516,712)	(398,598)	(275,218)
Total stockholders' equity	1,976,293	379,640	161,839	121,794	99,074

⁽¹⁾ In 2020 we completed the acquisition of four businesses, including ArcherDX, in 2019 we completed the acquisition of three businesses, and in 2017 we completed the acquisition of four businesses, all of which are included in our selected consolidated financial data as of the applicable acquisition date.

⁽²⁾ On January 1, 2019, we adopted Accounting Standards Codification, or ASC, Topic 842 using the modified retrospective transition method as of the adoption date which required the recognition of operating lease right-of-use assets and operating lease liabilities to be recognized on our consolidated balance sheets. Prior period amounts are presented as originally reported based upon the accounting standards in effect for those periods.

⁽³⁾ On January 1, 2018, we adopted ASC Topic 606 using the modified retrospective transition method. Prior period amounts are presented as originally reported based upon the accounting standards in effect for those periods.

⁽⁴⁾ Includes employee stock-based compensation as follows (in thousands):

	Year Ended December 31,				
	2020	2019	2018	2017	2016
Cost of revenue	\$ 8,713	\$ 4,563	\$ 2,960	\$ 2,093	\$ 1,353
Research and development	91,762	52,450	7,017	6,158	4,976
Selling and marketing	14,418	7,641	4,887	3,956	1,709
General and administrative	43,854	11,294	5,986	7,014	2,661
Total stock-based compensation	<u>\$ 158,747</u>	<u>\$ 75,948</u>	<u>\$ 20,850</u>	<u>\$ 19,221</u>	<u>\$ 10,699</u>

See Note 4, "Business combinations," and Note 10, "Stock incentive plans," in our audited consolidated financial statements included elsewhere in this report for further information regarding our stock-based compensation.

⁽⁵⁾ See Note 2, "Summary of significant accounting policies," and Note 12, "Net loss per share," in our audited consolidated financial statements included elsewhere in this report for an explanation of the calculations of our basic and diluted net loss per share.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes included in Item 8 of this report. Historic results are not necessarily indicative of future results.

Business overview

We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, personalized oncology, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets including four businesses in 2020, which expanded our suite of genome management offerings and established a broader entry into oncology therapy selection and personalized cancer monitoring.

In October 2020, we completed the acquisition of ArcherDX, Inc. ("ArcherDX"), a genomics company democratizing precision oncology by offering a suite of products and services that are accurate, personal, actionable and easy to use in local settings, thereby empowering clinicians to control the sample, data, patient care and economics. ArcherDX's development platform, including its proprietary Anchored Multiplex PCR, or AMP, chemistry at the core, is enabling clinical tests and services that allow for therapy selection and cancer monitoring in community locations for the first time at scale. In addition, applying these assets via biopharma partnerships may enable more efficient development of new cancer therapies, companion diagnostics and result in more productive clinical trial processes.

We have experienced rapid growth. For the years ended December 31, 2020, 2019 and 2018, our revenue was \$279.6 million, \$216.8 million and \$147.7 million, respectively and we incurred net losses of \$602.2 million, \$242.0 million and \$129.4 million, respectively. At December 31, 2020, our accumulated deficit was \$1.4 billion. To meet the demands of scaling our business, we increased our number of employees to approximately 2,100 at December 31, 2020 from approximately 1,300 at December 31, 2019. Our sales force grew to approximately 300 at December 31, 2020 from approximately 230 at December 31, 2019. We expect headcount will continue to increase as we add staff to support anticipated growth.

Sales of our tests have grown significantly. In 2020, 2019 and 2018, we generated 659,000, 469,000 and 292,000 billable units, respectively. We calculate volume using billable units, which are billable events that include individual test reports released and individual reactions shipped. We refer to the set of reagents needed to perform an NGS test as a "reaction." Through December 31, 2020, 46% of the billable units we performed have been billable to patients, biopharma partners and other business-to-business customers (e.g., hospitals, clinics, medical centers), and the remainder have been billable to third-party payers. Many of the gene tests on our assays are tests for which insurers reimburse. However, when we do not have reimbursement policies or contracts with private insurers, our claims for reimbursement may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. Even if we are successful in achieving reimbursement, we may be paid at lower rates than if we were under contract with the third-party payer. When there is not a contracted rate for reimbursement, there is typically a greater payment requirement from the patient that may result in further delay in payment for these tests.

We expect to incur operating losses for the near term as we continue to invest in our business to achieve our revenue growth objectives, including expansion of our platform to capture the broad potential of genetics across healthcare, and may need to raise additional capital in order to fund our operations. If we are unable to achieve these objectives and successfully manage our costs, we may not be able to achieve profitability in the near term or at all.

We believe that the keys to our future growth will be to increase billable volume, achieve broad reimbursement coverage for our tests from third-party payers, drive down the price for genetic analysis and interpretation, steadily increase the amount of genetic content we offer, consistently improve the client experience, drive physician and patient utilization of our website for ordering and delivery of results and increase the number of strategic partners working with us to add value for our clients. We also believe that providing a unique genetic testing platform that is agnostic to stage of life or disease category will deliver unique benefits to customers, payers and other institutions that are seeking to make genetic information a standard element of healthcare decisions in the future.

Impact of COVID-19

Our test volumes decreased significantly in the second half of March 2020 as compared to the first few months of 2020 as a result of COVID-19 and related limitations and priorities across the healthcare system. Our daily volumes have consistently increased from the low in March 2020, although we are currently still experiencing changes in product mix due to the impact of COVID-19. COVID-19 could have a material impact on our financial results for the foreseeable future, particularly on product mix and as a result, the revenue we recognize. We have reviewed and adjusted for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

In response to the pandemic we have implemented measures to protect the health of all of our employees during this time with additional measures in place to better protect our on-site lab production and support teams. Our production facilities currently remain fully operational. While we have not experienced significant disruption in our supply chain, over the past several months, we have experienced supply delays as a result of the COVID-19 pandemic and have also had to obtain supplies from new suppliers. Although we do not yet know the full impact COVID-19 will have on our supply chain, we have increased our inventory on hand to respond to potential future disruptions that may occur.

Many announced healthcare guidelines call for a shift of regular physician visits and healthcare delivery activities to remote/telehealth formats. This is particularly important for patients who, despite the fall-out from COVID-19, continue to be diagnosed with critical diseases, like cancer, and for women who are pregnant or are trying to conceive. We believe our investments in new access platforms and technologies will position us well to provide a range of testing to clinicians and patients using a "clinical care from afar" model. An example is our rollout in April 2020 of our Gia telehealth platform, which expands access to remote interaction between patients and clinicians as well as direct ordering of genetic tests. Such access helped to counteract some of the adverse in-office impacts of COVID-19, allowing continuation of key testing categories in a safe environment.

Given the unknown duration and extent of COVID-19's impact on our business, and the healthcare system in general, we are adapting our spending and investment levels to evolving market conditions, including focusing commercial execution on workflows that support remote ordering, online support and telehealth. Approximately 8% of our workforce as of March 2020 was impacted by a reduction in force in April 2020 in an initiative to manage costs and cash burn, which resulted in one-time costs in the second quarter of 2020 of \$3.8 million. In addition, effective May 2020, we reduced the salaries of our named executive officers by approximately 20%, which reductions ceased as of January 2021.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was signed into law which was a stimulus bill intended to bolster the economy, among other things, and provide assistance to qualifying businesses and individuals. The CARES Act included an infusion of funds into the healthcare system, and in April 2020, we received \$3.8 million as a part of this initiative. This payment was recognized as other income (expense), net in our consolidated statement of operations during the year ended December 31, 2020. We also received \$2.3 million during January 2021 which we recognized as other income (expense), net during the three months ended March 31, 2021. At this time, we are not certain of the availability, extent or impact of any future relief provided under the CARES Act.

Factors affecting our performance

Number of billable units

Our centralized test revenue is tied to the number of tests which we bill third-party payers, biopharmaceutical partners, other business-to-business customers (e.g., hospitals, clinics, medical centers), or patients. Our decentralized product revenue is tied to the number of individual reactions we ship biopharma partners and other business-to-business customers. We refer to the set of reagents needed to perform an NGS test as a "reaction," and we refer to billable events that include individual test reports released and individual reactions shipped as billable units. We typically bill for our services following delivery of the billable report derived from testing samples and interpreting the results. For units manufactured for use by customers in distributed facilities, we typically bill customers upon shipment of those units. Test orders are placed under signed requisitions or contractual agreements, as we often enter into contracts with biopharmaceutical partners, other business-to-business customers (e.g., hospitals, clinics, medical centers) and insurance companies that include pricing provisions under which such tests are billed. We incur the expenses associated with a unit in the period in which the unit is processed regardless of when payment is received with respect to that unit. We believe the number of billable units in any period is an important indicator of the growth in our testing business, and with time, this will translate into the number of customers accessing our platform.

Number and size of research and commercial partnerships

Pharma development services revenue, which we recognize within other revenue in our consolidated statements of operations, is generated primarily from services provided to biopharmaceutical companies and other partners and is related to companion diagnostic development, clinical research, and clinical trial services across the research, development, and commercialization phases of collaborations. The result of these relationships may include the development of new targeted companion diagnostics, which underscore and expand the need for genetic testing and in some cases may lead to intellectual property and/or revenue sharing opportunities with third-party partners.

In addition to research partnerships, we also seek to grow the number of biopharmaceutical partners and other business-to-business customers (e.g., hospitals, clinics, medical centers) for whom we provide testing technologies, analysis, supplies and expertise to institutions that provide independent testing services to customers in their respective regions.

Success obtaining and maintaining reimbursement

Our ability to increase volume and revenue will depend in part on our success achieving broad reimbursement coverage and laboratory service contracts for our tests from third-party payers and agreements with institutions and partners. Reimbursement may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary and cost-effective, as well as whether we are in contract, where we get paid more consistently and at higher rates. Because each payer makes its own decision as to whether to establish a policy or enter into a contract to reimburse for our testing services and specific tests, seeking these approvals is a time-consuming and costly process. In addition, clinicians and patients may decide not to order our tests if the cost of the test is not covered by insurance. Because we require an ordering physician to requisition a test, our revenue growth also depends on our ability to successfully promote the adoption of our testing services and expand our base of ordering clinicians. We believe that establishing coverage and obtaining contracts from third-party payers is an important factor in gaining adoption by ordering clinicians. Our arrangements for laboratory services with payers cover approximately 315 million lives, comprised of Medicare, all national commercial health plans, and Medicaid in most states, including California (Medi-Cal), our home state.

Ability to lower the costs associated with performing our tests

Reducing the costs associated with performing our genetic tests is both a focus and a strategic objective of ours. Over the long term, we will need to reduce the cost of raw materials by improving the output efficiency of our assays and laboratory processes, modifying our platform-agnostic assays and laboratory processes to use materials and technologies that provide equal or greater quality at lower cost, improve how we manage our materials, port some tests onto a next generation sequencing platform and negotiate favorable terms for our materials purchases. Our acquisition of Singular Bio, Inc. is a component of this objective and we expect the technology acquired in this transaction, once developed, to help decrease the costs associated with our NIPS offering. We also intend to continue to design and implement hardware and software tools that are designed to reduce personnel-related costs for both laboratory and clinical operations/medical interpretation by increasing personnel efficiency and thus lowering labor costs per test. Finally, we plan to reduce the cost of providing test equipment and software to laboratories and other facilities in the U.S. and internationally. Those efforts are designed to enable more rapid expansion of genetic testing and patient access, enlarging our geographic footprint outside the U.S. while achieving lower costs.

Ability to expand our genetic content and create new pathways to test

Our focus on reducing the average cost per test will have a countervailing force — increasing the number of tests we offer, the content of each test and the means to connect our testing services with patients and physicians. We intend to continue to expand our test menus by steadily releasing additional genetic content for the same or lower prices per test, ultimately leading to affordable whole genome services. The breadth and flexibility of our offering will be a critical factor in our ability to address new markets, including internationally, for genetic testing services. Both of these, in conjunction with our continued focus on strategic partnerships, will be important to our ability to continue to grow the volume of billable tests we deliver. We have and will continue to identify new ways to connect our testing services and information to patients. These include direct patient outreach and ordering capacity, the use of automated assistants for physician customers to assist with the ease of ordering and processing genetic tests and programs designed to reach underserved patient populations with genetic testing.

Investment in our business and timing of expenses

We plan to continue to invest in our genetic testing and information management business. We deploy state-of-the-art technologies in our genetic testing services, and we intend to continue to scale our infrastructure, including our testing capacity and information systems. We also expect to incur software development costs as we seek to further automate our laboratory processes and our genetic interpretation and report sign-out procedures, scale our customer service capabilities to improve our customers' experience, and expand the functionality of our website. We also expect to incur costs as we seek to provide the testing equipment and software necessary to enable decentralized genetic and genomic testing in the U.S. and internationally. We will incur costs related to marketing and branding as we spread our initiatives beyond our current customer base and focus on providing access to customers through our website. We plan to hire additional personnel as necessary to support anticipated growth, including software engineers, sales and marketing personnel, billing personnel, research and development personnel, medical specialists, biostatisticians and geneticists. We will also incur additional costs related to the expansion of our production facilities to accommodate growth and as we expand internationally. In addition, we expect to incur ongoing expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter as we focus on building out different aspects of our business.

How we recognize revenue

We generally recognize revenue on an accrual basis, which is when a customer obtains control of the promised goods or services, typically a test report. Accrual amounts recognized are based on estimates of the consideration that we expect to receive, and such estimates are adjusted and subsequently recorded until fully settled. Changes to such estimates may increase or decrease revenue recognized in future periods. Revenue from our tests may not be equal to billed amounts due to a number of factors, including differences in reimbursement rates, the amounts of patient payments, the existence of secondary payers and claim denials. Some test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with biopharmaceutical partners, other business-to-business customers (e.g., hospitals, clinics, medical centers) and insurance companies that include pricing provisions under which such tests are billed.

Pharma development service revenues are generated primarily from custom assay design services, sample processing activities and consultative inputs, which is separate from revenue generated by any related or unrelated product component. Revenue is recognized as samples are processed or scope of work is completed based on contracted agreements with those biopharmaceutical customer companies.

Under these collaborations we also generate revenue from achievement of milestones, provision of on-going support, and related pass-through costs and fees. We generally have distinct performance obligations for development milestones related to our development of a companion diagnostic device. We use a cost plus a margin approach to estimate the standalone value of our companion diagnostic development service performance obligations. Revenue is recognized over time using input or output methods based on our assessments of performance completed to date toward each milestone.

Financial overview

Revenue

We primarily generate revenue from testing services and sales of distributed precision oncology products. Customers are typically billed upon delivery of test results or shipment of products. We also generate revenue from development agreements with biopharmaceutical customers. Our ability to increase our revenue will depend on our ability to increase our market penetration, obtain FDA and other international regulatory authority approvals on future products and services offerings, obtain contracted reimbursement coverage from third-party payers, and grow our relationships with biopharmaceutical customers.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering our products and services and includes expenses for materials and supplies, personnel-related costs, freight, costs for lab services and clinical trial support, equipment and infrastructure expenses and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangibles, and utilities. We expect cost of revenue to generally increase in line with the increase in billable volume, however, we expect a future increase in amortization of acquired intangible assets that is not dependent on billed volume. We anticipate our cost per unit for existing tests will generally decrease over time due to the efficiencies we expect to gain as volume increases and from automation and other cost reductions. These reductions in cost per unit will likely be offset by new offerings which often have a higher costs per unit during the introductory phases before we are able to gain efficiencies. The cost per unit may fluctuate significantly from quarter to quarter.

Operating expenses

Our operating expenses are classified into three categories: research and development, selling and marketing, and general and administrative. For each category, the largest component is generally personnel-related costs, which include salaries, employee benefit costs, bonuses, commissions, as applicable, and stock-based compensation expense.

Research and development

Research and development expenses represent costs incurred to develop our technology and future offerings. These costs are principally for process development associated with our efforts to expand the number of genes we can evaluate, our efforts to lower the costs per unit and our development of new products to expand our platform. In addition, we incur process development costs to further develop the software we use to operate our laboratories, analyze generated data, process customer orders, validate clinical activities, enable ease of customer ordering, deliver reports and automate our business processes. These costs consist of personnel-related costs, including stock-based compensation, laboratory supplies and equipment expenses, consulting costs, amortization of acquired intangible assets, and allocated overhead including rent, information technology, equipment depreciation and utilities.

We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to increase as we continue our efforts to develop additional offerings, make investments to reduce costs, streamline our technology to provide patients access to testing, scale our business domestically and internationally and acquire and integrate new technologies, including those acquired through our acquisition of ArcherDX.

During June 2019 through our acquisition of Singular Bio, we recognized \$30.0 million of in-process R&D technology using an income approach. This technology is estimated to be developed in 2021 with significant development costs incurred during the second half of 2019 through 2020 and expected through development completion. If not completed timely, the ability to lower the cost of our NIPS offering may be delayed. During October 2020 through our acquisition of ArcherDX, we recognized \$512.4 million of in-process R&D technology for two assets representing STRATAFIDE and Personalized Cancer Monitoring, or PCM, technologies, both using an income approach. We estimate these technologies to be developed in the next few years with significant development costs through completion.

Selling and marketing

Selling and marketing expenses consist of personnel-related costs, including commissions, client service expenses, advertising and marketing expenses, educational and promotional expenses, market research and analysis, and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangibles, and utilities. We expect our selling and marketing expenses to increase as we continue to build our brand and focus on advertising our products and services.

General and administrative

General and administrative expenses include executive, finance and accounting, billing and collections, legal and human resources functions as well as other administrative costs. These expenses include personnel-related costs; audit, accounting and legal expenses; consulting costs; allocated overhead including rent, information technology, equipment depreciation, and utilities; costs incurred in relation to our co-development agreements; changes in the fair value of contingent consideration related to our acquisitions; and post-combination expenses incurred in relation to companies we acquire. We expect our general and administrative expenses to increase as we support continued growth of operations.

Other expense, net

Other expense, net, primarily consists of adjustments to the fair value of our stock payable liabilities arising from business combinations, and we expect it to fluctuate significantly from period to period due to the volatility of our common stock. Other expense, net also includes income generated from our cash equivalents and marketable securities and amounts received under the CARES Act.

Interest expense

Interest expense is primarily attributable to interest incurred related to our debt financings and finance leases. See Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report for more details.

Income tax benefit

Since we generally establish a full valuation allowance against our deferred tax balances, our income tax benefit primarily consists of tax impacts of our deferred income tax assessments resulting from our acquisitions.

Critical accounting policies and estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. We evaluate our estimates on an ongoing basis. Our estimates are based on current facts, our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue recognition

We recognize revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers. We utilize the following practical expedients and exemptions:

- Costs to obtain or fulfill a contract are expensed when incurred because the amortization period would have been one year or less, and
- No adjustments to promised consideration were made for financing as we expect, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

Test revenue

Test revenue is comprised of testing services and sales of distributed precision oncology products.

The majority of our test revenue is generated from genetic testing, in addition to somatic testing for therapy selection and personalized cancer monitoring. These testing services provide analysis and associated interpretation of the sequencing of parts of the genome. Test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with biopharmaceutical partners, other business-to-business customers (e.g., hospitals, clinics, medical centers) and insurance companies that include pricing provisions under which such tests are billed. Billing terms are generally net 30 to 60 days.

While the transaction price of diagnostic tests is originally established either via contract or pursuant to our standard list price, we often provide concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which we will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur. Making these estimates requires significant judgments based upon such factors as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. These judgments are reviewed each reporting period and updated as necessary.

We look to transfer of control in assessing timing of recognition of revenue in connection with each performance obligation. In general, revenue in connection with the service portion of our diagnostic tests is recognized upon delivery of the underlying clinical report or when the report is made available on our web portal. Outstanding performance obligations pertaining to orders received but for which the underlying report has not been issued are generally satisfied within a 30-day period.

We also generate test revenue through the sale of our precision oncology products, which is comprised primarily of sales of our distributed RUO and IVD products for therapy selection. We recognize revenue on these sales once shipment has occurred. Product sales are recorded net of discounts and other deductions. Billing terms are generally net 30 days.

Shipping and handling fees billed to customers are classified on the consolidated statements of operations and comprehensive loss in revenue. The associated shipping and handling costs are classified in cost of revenue.

Other revenue

Other revenue is primarily generated from pharma development services provided to biopharmaceutical companies related to companion diagnostic development as well as through collaboration agreements and genome network contracts.

Contracts for companion diagnostic development consist primarily of milestone-based payments along with annual fees and marked-up pass-through costs. The arrangements are treated as short-term contracts for revenue recognition purposes because they allow termination of the agreements by the customers with 30 to 120 days' written notice without a termination penalty. Upon termination, customers are required to pay for the proportion of services provided under milestones that were in progress. We recognize revenue in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenue over time based on the progress made toward achieving the performance obligation, utilizing both input or output methods, depending on the performance obligation, including labor hours expended, tests processed, or time elapsed, that measure our progress toward the achievement of the milestone.

We also enter into collaboration and genome network contracts. Collaboration agreements provide customers with diagnostic testing and related data aggregation reporting services that are provided over the contract term. Collaboration revenue is recognized as the data and reporting services are delivered to the customer. Genome network offerings consist of subscription services related to a proprietary software platform designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis and treatment of hereditary disease. Such services are recognized on a straight-line basis over the subscription periods. Amounts due under collaboration and genome network agreements are typically billable on net 30-day terms.

Business combinations

We apply Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC 805, *Business Combinations*, which requires recognition of assets acquired, liabilities assumed, and contingent consideration at their fair value on the acquisition date with subsequent changes recognized in earnings; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination and expensed as incurred; requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset until completion or abandonment; and requires that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of provision for taxes.

We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. We base the estimated fair value of identifiable intangible assets acquired in a business combination on third-party valuations that use information and assumptions provided by our management, which consider our estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, estimated cost savings, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under ASC Topic 480, *Distinguishing Liabilities from Equity*, we recognize a liability equal to the fair value of the contingent payments we expect to make as of the acquisition date. We remeasure this liability each reporting period and record changes in the fair value as a component of operating expenses.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in our operating results from the date of acquisition.

Goodwill

In accordance with ASC 350, *Intangibles - Goodwill and Other*, or ASC 350, we do not amortize goodwill or other intangible assets with indefinite lives but rather test them for impairment. ASC 350 requires us to perform an impairment review of our goodwill balance at least annually, which we do in the fourth quarter of each year for our single consolidated reporting unit, and whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. We did not incur any goodwill impairment losses in any of the periods presented.

Stock-based compensation

We incur stock-based compensation expense for awards granted to employees and directors and for inducement awards granted in connection with our business acquisitions. Stock-based compensation expense is measured at the date of grant and is based on the estimated fair value of the award. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and restricted stock unit, or RSU, awards and on an accelerated basis for performance-based restricted stock unit, or PRSU, awards. We recognize stock-based compensation expense associated with PRSU grants when we determine the achievement of performance conditions is probable. In determining the fair value of stock options and Employee Stock Purchase Plan, or ESPP, purchases, we estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. We estimate the grant date fair value of RSU and PRSU awards based on the grant date share price.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of stock-based awards. These assumptions include:

Expected term—The expected term represents the period that stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is based on the mid-point between the vesting date and the end of the contractual term.

Expected volatility—We estimate expected volatility based on the historical volatility of our common stock over a period equal to the expected term of awards and over the expected six-month term ESPP purchase periods.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of an option.

Dividend yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods.

Income taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Significant judgment is required in determining the net valuation allowance which includes our evaluation of all available evidence including past operating results, estimates on future taxable income and acquisition-related tax assets and liabilities. As of December 31, 2020, we recorded a full valuation allowance on our net deferred tax assets because we expect that it is more likely than not that our deferred tax assets will not be realized in the foreseeable future. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted.

Results of operations

A discussion regarding our financial condition and results of operations for the year ended December 31, 2020 compared to the year ended December 31, 2019 is presented below. A discussion regarding our financial condition and results of operations for the year ended December 31, 2019 compared to the year ended December 31, 2018 can be found under Part II, Item 7 in our Annual Report on Form 10-K for the year ended December 31, 2019.

Comparison of the Years Ended December 31, 2020 and 2019

	Year Ended December 31,		Dollar Change	% Change
	2020	2019		
Revenue:				
Test revenue	\$ 272,310	\$ 212,473	\$ 59,837	28%
Other revenue	7,288	4,351	2,937	68%
Total revenue	279,598	216,824	62,774	29%
Cost of revenue	198,275	118,103	80,172	68%
Research and development	240,605	141,526	99,079	70%
Selling and marketing	168,317	122,237	46,080	38%
General and administrative	324,573	79,070	245,503	310%
Loss from operations	(652,172)	(244,112)	(408,060)	167%
Other expense, net	(32,332)	(3,891)	(28,441)	731%
Interest expense	(29,766)	(12,412)	(17,354)	140%
Net loss before taxes	(714,270)	(260,415)	(453,855)	174%
Income tax benefit	(112,100)	(18,450)	(93,650)	508%
Net loss	\$ (602,170)	\$ (241,965)	\$ (360,205)	149%

Revenue

The increase in revenue of \$62.8 million for the year ended December 31, 2020 compared to the same period in 2019 was due primarily to increased billable volume from growth in our business as well as the contribution from businesses acquired in 2020, including ArcherDX in the fourth quarter of 2020. Billable units increased to approximately 659,000 during the year ended December 31, 2020 compared to 469,000 in the same period in 2019, an increase of 41%. Average revenue per unit decreased to \$413 during the year ended December 31, 2020 compared to \$453 in the same period in 2019, primarily due to changes in payer and product mix, the impact of the businesses acquired during 2020, particularly ArcherDX, as well as reductions in pricing for some payers as we focus on providing cost effective genetic testing.

Cost of revenue

The increase in the cost of revenue of \$80.2 million for the year ended December 31, 2020 compared to the same period in 2019 was primarily due to costs associated with increased billable volume and the added costs related to businesses acquired in 2020, partially offset by the effect of cost efficiencies. For the year ended December 31, 2020, the number of units billed increased to approximately 659,000 from approximately 469,000 for the same period in 2019. Cost per billable unit was \$299 in 2020 compared to \$252 in 2019. The cost per unit increased primarily due to an increase in amortization of acquired intangible assets by \$17.5 million as well as increased stock-based compensation by \$4.2 million. The increase in the cost per unit was also due to changes in product mix, including the impact of the cost per unit of ArcherDX, as well as the influence of COVID-19. The increases were partially offset by production improvements that resulted in material efficiencies and automation and software improvements which reduced the medical interpretation time per report.

Research and development

The increase in research and development expense of \$99.1 million for the year ended December 31, 2020 compared to the same period in 2019 was due to growth in the business and the effect of business acquisitions in 2020 and principally consisted of increases in personnel-related costs by \$87.7 million, reflecting increased headcount as well as a \$39.3 million increase in stock-based compensation; an increase in general lab expenses by \$8.4 million; an increase in information technology costs by \$4.8 million due to increased spending on networking equipment and software licenses; an increase by \$4.7 million in professional fees; an increase by \$2.4 million of depreciation and amortization; and an increase by \$1.9 million in occupancy expenses. These cost increases were partially offset by a net increase of \$9.6 million in allocations of resources from research and development to cost of revenue to support the increase in production volumes as well as a decrease in travel-related costs by \$1.3 million due to a reduction in travel as a result of COVID-19.

Selling and marketing

The increase in selling and marketing expenses of \$46.1 million for the year ended December 31, 2020 compared to the same period in 2019 was due to growth in the business and the effect of business acquisitions in 2020 and principally consisted of the following elements: an increase in personnel costs by \$40.6 million due to increases in headcount; an increase by \$3.7 million in allocations from other functional areas; an increase in marketing costs, principally for branding initiatives and advertising, by \$2.0 million; an increase in information technology costs by \$1.4 million; an increase in professional fees by \$1.2 million; and an increase in depreciation and amortization by \$1.2 million. These cost increases were partially offset by a decrease in travel expenses of \$4.1 million due to a reduction in travel as a result of COVID-19.

General and administrative

The increase in general and administrative expenses of \$245.5 million for the year ended December 31, 2020 compared to the same period in 2019 was primarily due to the growth of the business and the effect of business acquisitions in 2020 and principally consisted of the following elements: an increase in acquisition-related expense by \$140.1 million, which includes \$125.8 million of post-combination expense related to the acceleration of unvested equity from our acquisition of ArcherDX; an increase in fair value adjustments to contingent consideration by \$54.4 million, primarily related to the development milestones for ArcherDX; an increase in personnel-related costs by \$46.5 million primarily due to increases in headcount; an increase in legal and accounting costs by \$5.2 million; an increase in information technology costs by \$2.7 million due primarily to computer equipment and software purchases to support headcount growth; and an increase in depreciation and amortization by \$0.9 million.

These cost increases were offset by increased allocations of technology and facilities-related expenses to other functional areas of \$7.1 million.

Other expense, net

The increase in other expense, net of \$28.4 million for the year ended December 31, 2020 compared to the same period in 2019 was principally due to fair value adjustments related to our stock payable liabilities of \$37.5 million due to the increase in the price of our common stock partially offset by a reduction of debt extinguishment costs of \$8.9 million incurred in September 2019 with no similar expense in 2020, \$3.8 million received under the CARES Act during 2020, and decreases in interest income from our cash equivalents and marketable securities.

Interest expense

The increase in interest expense of \$17.4 million for the year ended December 31, 2020 compared to the same period in 2019 was due principally to increased borrowings under our debt facilities as compared to the prior year period. See Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

Income tax benefit

The increase in income tax benefit of \$93.7 million for the year ended December 31, 2020 compared to the same period in 2019 was due to net deferred tax liabilities assumed in connection with our acquisitions of YouScript Incorporated and ArcherDX which provided a future source of income to support the realization of our deferred tax assets and resulted in a partial release of our valuation allowance. As the short period tax returns for our 2020 acquisitions have not yet been filed, material changes to the tax returns may have a material impact on the net deferred tax liabilities assumed in connection with the acquisitions and the related income tax benefit.

Liquidity and capital resources

Liquidity and capital expenditures

We have incurred net losses since our inception. For the years ended December 31, 2020, 2019 and 2018, our net losses were \$602.2 million, \$242.0 million and \$129.4 million, respectively, and we expect to incur additional losses in the future. At December 31, 2020, we had an accumulated deficit of \$1.4 billion. While our revenue has increased over time, we may never achieve revenue sufficient to offset our expenses.

Since inception, our operations have been financed primarily by fees collected from our customers, net proceeds from sales of our capital stock as well as borrowing from debt facilities and the issuance of Convertible Senior Notes.

In March 2019, we issued, in an underwritten public offering, an aggregate of 10.4 million shares of our common stock at a price of \$19.00 per share, for gross proceeds of \$196.7 million and net proceeds of \$184.5 million. During 2019, we issued 0.8 million shares of common stock at an average price of \$25.71 per share in "at the market" offerings for aggregate proceeds of \$20.2 million and net proceeds of \$19.5 million. In April 2020, we issued, in an underwritten public offering, an aggregate of 20.4 million shares of our common stock at a price of \$9.00 per share, for gross proceeds of \$184.0 million and net proceeds of approximately \$173.0 million. In 2020, we issued approximately 3.6 million shares of common stock at an average price of \$26.33 per share in an "at the market" offering for aggregate proceeds of \$93.7 million and net proceeds of \$90.7 million. In January 2021, we issued, in an underwritten public offering, an aggregate of 8.9 million shares of our common stock at a price of \$51.50 per share, for gross proceeds of \$460.0 million and net proceeds of approximately \$434.3 million.

In September 2019, we issued \$350.0 million of aggregate principal amount of Convertible Senior Notes, which bear cash interest at a rate of 2.0% per year. Also in September 2019, we used the funds received through the issuance of our Convertible Senior Notes to settle our Note Purchase Agreement we entered into in November 2018.

In October 2020 in connection with our acquisition of ArcherDX, we issued \$275.0 million of our common stock in a private placement at a price of \$16.85 per share to a syndicate of life sciences investors. We also entered into a credit facility to borrow \$135.0 million. The private placement and credit facility closed concurrently with the merger in October 2020. In connection with the credit facility, we issued warrants to purchase 1.0 million shares of our common stock at an exercise price of \$16.85 per share which were exercised in October 2020 on a net exercise basis. The terms of this credit facility restrict our ability to incur certain indebtedness, pay dividends, make acquisitions and take other actions.

At December 31, 2020 and 2019, we had \$360.7 million and \$398.0 million, respectively, of cash, cash equivalents, restricted cash and marketable securities.

Our primary uses of cash are to fund our operations as we continue to grow our business, enter into partnerships and acquire businesses and technologies. Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We estimate our capital expenditures will be approximately \$30.0 million for 2021.

We have incurred substantial losses since inception, and we expect to continue to incur losses in the future. We believe our existing cash, cash equivalents and marketable securities as of December 31, 2020 and fees collected from the sale of our tests will be sufficient to meet our anticipated cash requirements for the foreseeable future.

We may need additional funding to finance operations prior to achieving profitability or should we make additional acquisitions. We regularly consider fundraising opportunities and will determine the timing, nature and size of future financings based upon various factors, including market conditions and our operating plans. We may in the future elect to finance operations by selling equity or debt securities or borrowing money. We also may elect to finance future acquisitions. If we issue equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing additional debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. In addition, the terms of additional debt securities or borrowings could impose significant restrictions on our operations. If additional funding is required, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all. If we are unable to obtain additional funding when needed, we may need to curtail planned activities to reduce costs. Doing so will likely have an unfavorable effect on our ability to execute on our business plan and have an adverse effect on our business, results of operations and future prospects.

The following table summarizes our cash flows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Cash used in operating activities	\$ (298,502)	\$ (145,053)	\$ (92,220)
Cash provided by (used in) investing activities	(400,583)	(280,310)	35,773
Cash provided by financing activities	672,993	464,771	157,152
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ (26,092)</u>	<u>\$ 39,408</u>	<u>\$ 100,705</u>

Cash flows from operating activities

For the year ended December 31, 2020, cash used in operating activities was \$298.5 million and principally resulted from our net loss of \$602.2 million and \$112.1 million related to our income tax benefit generated from business combinations completed in 2020 partially offset by non-cash charges of \$158.7 million for stock-based compensation, \$92.3 million in remeasurements of liabilities associated with business combinations such as contingent consideration, \$91.0 million related to post-combination expense due to the acceleration of unvested equity in the acquisition of ArcherDX, \$39.1 million for depreciation and amortization, \$17.2 million of amortization of debt discount and issuance costs and \$1.4 million of other adjustments. The net effect on cash for changes in net operating assets was an inflow of cash of \$16.0 million due principally to increases in accounts payable and accrued liabilities partially offset by increases in inventory and accounts receivable due to timing of collections.

For the year ended December 31, 2019, cash used in operating activities of \$145.1 million principally resulted from our net loss of \$242.0 million and \$18.5 million related to our income tax benefit generated from business combinations completed in 2019 offset by non-cash charges of \$75.9 million for stock-based compensation, \$16.2 million for depreciation and amortization, \$8.9 million for debt extinguishment costs related to the settlement of our 2018 Note Purchase Agreement and \$1.1 million of other adjustments. The net effect on cash for changes in net operating assets was a use of cash of \$8.8 million due principally to increases in accrued liabilities which include acquisition-related liabilities for 2019 business acquisitions partially offset by increases in accounts receivable due to timing of collections and increases in prepaid expenses and other current assets.

For the year ended December 31, 2018, cash used in operating activities of \$92.2 million principally resulted from our net loss of \$129.4 million offset by non-cash charges of \$20.9 million for stock-based compensation, \$13.5 million for depreciation and amortization, \$5.3 million related to debt extinguishment costs, \$2.9 million of impairment losses related to a collaboration agreement, \$0.8 million of other non-cash adjustments and \$0.4 million for remeasurements of liabilities associated with business combinations, all partially offset by a \$2.9 million benefit from income taxes resulting from the completion of our analysis of historical net operating losses for CombiMatrix Corporation. The net effect on cash of changes in net operating assets was a use of cash of \$3.8 million due principally to the effect of increase in accounts receivable due to timing of collections partially offset by an increase in accrued and other liabilities.

Cash flows from investing activities

For the year ended December 31, 2020, cash used in investing activities of \$400.6 million was primarily related to net cash used to acquire Orbicule BV ("Diploid"), Genelex, YouScript and ArcherDX of \$383.8 million, purchases of property and equipment of \$22.9 million, and other cash outflows of \$4.0 million, all partially offset by net sales and maturities of marketable securities of \$10.1 million.

For the year ended December 31, 2019, cash used in investing activities of \$280.3 million resulted primarily from purchases of marketable securities exceeding proceeds from maturities and sales of marketable securities by \$226.4 million, net cash used to acquire Singular Bio, Jungla Inc., and Clear Genetics, Inc. of \$33.8 million and purchases of property and equipment of \$20.0 million.

For the year ended December 31, 2018, cash provided by investing activities of \$35.8 million resulted primarily from proceeds from maturities and sales of marketable securities exceeding purchases of marketable securities by \$42.7 million and purchases of property and equipment of \$6.0 million.

Cash flows from financing activities

For the year ended December 31, 2020, cash provided by financing activities of \$673.0 million consisted of cash received from issuances of common stock totaling \$284.2 million, including cash received from shares issued through a private placement in October 2020 upon the close of the ArcherDX acquisition, exercises of stock options and employee stock plan purchases; net proceeds from the public offerings of common stock of \$263.7 million; and net proceeds from debt financings of \$129.2 million. These cash inflows were partially offset by other cash outflows of \$4.1 million.

For the year ended December 31, 2019, cash provided by financing activities of \$464.8 million consisted of net proceeds from the issuance of Convertible Senior Notes of \$339.9 million, net proceeds from the public offerings of common stock of \$204.0 million and cash received from issuances of common stock totaling \$9.5 million, including cash received from exercises of stock options of \$3.5 million and employee stock plan purchases of \$5.8 million. These cash inflows were partially offset by payments related to the settlement of our Note Purchase Agreement through repayment of loan obligations of \$75.0 million and payment of debt extinguishment costs of \$10.6 million, as well as finance lease payments of \$2.1 million.

For the year ended December 31, 2018, cash provided by financing activities of \$157.2 million consisted of net proceeds from the public offerings of common stock of \$112.4 million, net proceeds of \$93.9 million from the second term loan under the Amended 2017 Loan Agreement and from the 2018 Note Purchase Agreement, and cash received from issuances of common stock totaling \$17.5 million (which includes \$6.5 million received from exercises of warrants issued pursuant to the acquisition of CombiMatrix, \$5.0 million received pursuant to the Securities Purchase Agreement entered into in connection with our 2018 Note Purchase Agreement, employee stock purchases of \$3.2 million, and stock option exercises of \$2.7 million). These cash inflows were partially offset by loan payments of \$60.0 million to extinguish our 2017 Loan Agreement, payments of \$4.6 million related to the extinguishment of our 2017 Loan Agreement and related amendments and capital lease payments of \$2.1 million.

Contractual obligations

The following table summarizes our contractual obligations, including interest, as of December 31, 2020 (in thousands):

Contractual obligations:	2021	2022 and 2023	2024 and 2025	2026 and beyond	Total
Operating leases	\$ 14,338	\$ 27,017	\$ 25,079	\$ 9,499	\$ 75,933
Finance leases	2,006	3,107	26	—	5,139
Convertible Senior Notes	—	—	350,000	—	350,000
2020 Term Loan	—	—	135,000	—	135,000
Purchase commitments	23,064	39,823	13,750	25,501	102,138
Total	\$ 39,408	\$ 69,947	\$ 523,855	\$ 35,000	\$ 668,210

See Note 8, “Commitments and contingencies” in Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report for additional details regarding our leases, Convertible Senior Notes, 2020 Term Loan and purchase commitments.

Off-balance sheet arrangements

We have not entered into any off-balance sheet arrangements.

Recent accounting pronouncements

See “Recent accounting pronouncements” in Note 2, “Summary of significant accounting policies” in the Notes to Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and accounting pronouncements not yet adopted, and their expected effect on our financial position and results of operations.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. Our cash, cash equivalents, restricted cash and marketable securities totaled \$360.7 million at December 31, 2020, and consisted primarily of money market funds, U.S. treasury notes, and U.S. government agency securities. Such interest-bearing instruments carry a degree of risk; however, because our investments are primarily high-quality credit instruments with short-term durations with high-quality institutions, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. At December 31, 2020, a hypothetical 1.0% (100 basis points) increase or decrease in interest rates would not have resulted in a material change in the fair value of our cash equivalents and portfolio of marketable securities. Fluctuations in the value of our cash equivalents and portfolio of marketable securities caused by a change in interest rates (gains or losses on the carrying value) are recorded in other comprehensive gain (loss) and are realized only if we sell the underlying securities prior to maturity or declines in fair value are determined to be other-than-temporary.

Our 2020 Term Loan bears interest at an annual rate equal to LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75% and is therefore sensitive to changes in interest rates. We currently do not use interest rate derivative instruments to manage our exposure to interest rate fluctuations.

Although our Convertible Senior Notes are based on a fixed rate, changes in interest rates could impact their fair market value. As of December 31, 2020, the fair market value of the Convertible Senior Notes was \$586.0 million. For additional information about the Convertible Senior Notes, see Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

ITEM 8. Consolidated Financial Statements and Supplementary Data.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Invitae Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Invitae Corporation (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 26, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Measurement of test revenue

Description of the Matter During the year ended December 31, 2020, the Company's test revenue subject to estimation was \$181.0 million. As discussed in Note 3 of the consolidated financial statements, test revenue is recognized when the performance obligation is complete, generally upon delivery of the underlying clinical report or when the report is made available to the customer on the Company's website.

The amounts recognized are based on estimates of the consideration that the Company expects to receive, and such estimates are adjusted and subsequently recorded until fully settled. Auditing the measurement of the Company's test revenue was complex and judgmental due to the significant estimation required in determining the amount expected to be collected for each test. In particular, the estimate of revenue for tests billed to insurance carriers is affected by assumptions in payer behavior such as changes in historical payment patterns, contract provisions and government and private insurance reimbursement policies.

How We Addressed the Matter in Our Audit We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's revenue recognition process. As part of our testing, we considered controls over management's review of the significant assumptions and inputs used in the determination of the amount expected to be collected. We also tested controls used by management to compare the current and historical data used in making the estimates for completeness and accuracy.

Our audit procedures over the Company's test revenue included, among others, assessing valuation methodologies and models and testing the significant assumptions above and the underlying data used by the Company in its analysis. We agreed a sample of transactions to the payer contract terms. We compared the significant assumptions above and inputs used by management to changes in the Company's contracted rates, government and private insurance payer collection trends, and other relevant factors. We assessed the historical accuracy of the cash collections used in the Company's revenue models and assessed the completeness of adjustments to estimates of future cash collections as a result of significant contract amendments and changes in collection trends.

Valuation of intangible assets associated with business acquisitions

Description of the Matter As described in Note 4 to the consolidated financial statements, the Company completed several business acquisitions during 2020. As a result of the acquisitions, the Company recorded goodwill of \$1,736.8 million, and intangible assets of \$880.4 million. The acquisitions were accounted for as business combinations.

Auditing the Company's accounting for the acquisitions was challenging as the determination of the fair value of the intangible assets acquired required management to make subjective estimates and assumptions. The Company used an income approach to measure the acquired intangible assets. The valuation of the intangible assets is subject to higher estimation uncertainty due to management's judgments in determining significant assumptions that included assumed revenue growth, estimated cost savings and discount rates. Changes in these significant assumptions could have a significant effect on the fair value of the intangible assets.

How We Addressed the Matter in Our Audit We tested the design and operating effectiveness of internal controls over the Company's process for accounting for acquisitions. For example, we tested controls over management's review of the valuation of intangible assets, including the review of the valuation model and significant assumptions used in the valuation.

Our audit procedures related to the valuation of intangible assets included, among others, utilizing a valuation specialist to assist in evaluating the appropriateness of the Company's valuation models and evaluating the reasonableness of significant assumptions used such as the revenue growth, estimated cost savings and the discount rates as compared to industry and market data and historical results. We also evaluated whether the assumptions used were reasonable by comparing them to the past performance of prior acquisitions, current industry data and current market forecasts, and whether such assumptions were consistent with evidence obtained in other areas of the audit.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.

Redwood City, California

February 26, 2021

INVITAE CORPORATION

Consolidated Balance Sheets

(in thousands, except par value data)

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 124,794	\$ 151,389
Marketable securities	229,186	240,436
Accounts receivable	47,722	32,541
Inventory	32,030	6,648
Prepaid expenses and other current assets	20,200	11,384
Total current assets	<u>453,932</u>	<u>442,398</u>
Property and equipment, net	66,102	37,747
Operating lease assets	45,109	36,640
Restricted cash	6,686	6,183
Intangible assets, net	981,845	125,175
Goodwill	1,863,623	126,777
Other assets	13,188	6,681
Total assets	<u>\$ 3,430,485</u>	<u>\$ 781,601</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 25,203	\$ 10,321
Accrued liabilities	86,058	64,814
Operating lease obligation	8,789	4,870
Finance lease obligation	1,695	1,855
Total current liabilities	<u>121,745</u>	<u>81,860</u>
Operating lease obligation, net of current portion	48,357	42,191
Finance lease obligation, net of current portion	3,123	1,155
Debt	104,449	—
Convertible senior notes, net	283,724	268,755
Deferred tax liability	51,538	—
Other long-term liabilities	841,256	8,000
Total liabilities	<u>1,454,192</u>	<u>401,961</u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value: 20,000 shares authorized; 125 shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, \$0.0001 par value: 400,000 shares authorized; 185,886 and 98,796 shares issued and outstanding as of December 31, 2020 and 2019, respectively	19	10
Accumulated other comprehensive income (loss)	1	(9)
Additional paid-in capital	3,337,120	1,138,316
Accumulated deficit	(1,360,847)	(758,677)
Total stockholders' equity	<u>1,976,293</u>	<u>379,640</u>
Total liabilities and stockholders' equity	<u>\$ 3,430,485</u>	<u>\$ 781,601</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Operations

(in thousands, except per share data)

	Year Ended December 31,		
	2020	2019	2018
Revenue:			
Test revenue	\$ 272,310	\$ 212,473	\$ 144,560
Other revenue	7,288	4,351	3,139
Total revenue	<u>279,598</u>	<u>216,824</u>	<u>147,699</u>
Cost of revenue	198,275	118,103	80,105
Research and development	240,605	141,526	63,496
Selling and marketing	168,317	122,237	74,428
General and administrative	324,573	79,070	52,227
Loss from operations	<u>(652,172)</u>	<u>(244,112)</u>	<u>(122,557)</u>
Other expense, net	(32,332)	(3,891)	(2,568)
Interest expense	(29,766)	(12,412)	(7,030)
Net loss before taxes	<u>(714,270)</u>	<u>(260,415)</u>	<u>(132,155)</u>
Income tax benefit	(112,100)	(18,450)	(2,800)
Net loss	<u>\$ (602,170)</u>	<u>\$ (241,965)</u>	<u>\$ (129,355)</u>
Net loss per share, basic and diluted	<u>\$ (4.47)</u>	<u>\$ (2.66)</u>	<u>\$ (1.94)</u>
Shares used in computing net loss per share, basic and diluted	<u>134,587</u>	<u>90,859</u>	<u>66,747</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Comprehensive Loss

(in thousands)

	Year Ended December 31,		
	2020	2019	2018
Net loss	\$ (602,170)	\$ (241,965)	\$ (129,355)
Other comprehensive income (loss):			
Unrealized income (loss) on available-for-sale marketable securities, net of tax	10	(4)	166
Comprehensive loss	<u>\$ (602,160)</u>	<u>\$ (241,969)</u>	<u>\$ (129,189)</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Stockholders' Equity

(in thousands)

	Year Ended December 31,		
	2020	2019	2018
Common stock:			
Balance, beginning of period	\$ 10	\$ 8	\$ 5
Common stock issued	9	2	3
Balance, end of period	<u>19</u>	<u>10</u>	<u>8</u>
Accumulated other comprehensive income (loss):			
Balance, beginning of period	(9)	(5)	(171)
Unrealized income (loss) on available-for-sale marketable securities, net of tax	10	(4)	166
Balance, end of period	<u>1</u>	<u>(9)</u>	<u>(5)</u>
Additional paid-in capital:			
Balance, beginning of period	1,138,316	678,548	520,558
Common stock issued in private placement, net	263,628	—	5,353
Common stock issued in connection with public offering, net	263,685	204,024	112,438
Common stock issued on exercise of stock options, net	10,730	3,456	2,741
Common stock issued pursuant to exercises of warrants	974	181	6,539
Common stock issued pursuant to employee stock purchase plan	8,871	5,833	3,231
Common stock issued or issuable pursuant to acquisitions	1,524,227	133,942	6,455
Equity component of convertible senior notes, net	—	75,488	—
Warrants issued pursuant to loan agreement	27,000	—	383
Stock-based compensation expense	110,076	36,844	20,850
Reclassification of stock payable liabilities	(10,387)	—	—
Balance, end of period	<u>3,337,120</u>	<u>1,138,316</u>	<u>678,548</u>
Accumulated deficit:			
Balance, beginning of period	(758,677)	(516,712)	(398,598)
Cumulative effect of accounting change	—	—	11,241
Net loss	(602,170)	(241,965)	(129,355)
Balance, end of period	<u>(1,360,847)</u>	<u>(758,677)</u>	<u>(516,712)</u>
Total stockholders' equity	<u>\$ 1,976,293</u>	<u>\$ 379,640</u>	<u>\$ 161,839</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2020	2019	2018
Cash flows from operating activities:			
Net loss	\$ (602,170)	\$ (241,965)	\$ (129,355)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	39,050	16,206	13,540
Stock-based compensation	158,747	75,948	20,850
Amortization of debt discount and issuance costs	17,204	4,416	—
Impairment losses	—	—	2,925
Remeasurements of liabilities associated with business combinations	92,348	—	—
Benefit from income taxes	(112,100)	(18,450)	(2,862)
Debt extinguishment costs	—	8,926	5,266
Post-combination expense for acceleration of unvested equity	91,021	—	—
Other	1,425	1,095	1,168
Changes in operating assets and liabilities, net of businesses acquired:			
Accounts receivable	(2,814)	(6,131)	(5,291)
Inventory	(7,832)	1,645	(2,848)
Prepaid expenses and other current assets	(2,010)	(6,624)	1,403
Other assets	895	2,026	(163)
Accounts payable	10,186	1,558	(417)
Accrued expenses and other long-term liabilities	17,548	16,297	3,564
Net cash used in operating activities	<u>(298,502)</u>	<u>(145,053)</u>	<u>(92,220)</u>
Cash flows from investing activities:			
Purchases of marketable securities	(280,258)	(260,917)	(9,680)
Proceeds from sales of marketable securities	12,832	—	19,965
Proceeds from maturities of marketable securities	277,487	34,500	32,458
Acquisition of businesses, net of cash acquired	(383,753)	(33,846)	—
Purchases of property and equipment	(22,865)	(20,047)	(5,970)
Other	(4,026)	—	(1,000)
Net cash provided by (used in) investing activities	<u>(400,583)</u>	<u>(280,310)</u>	<u>35,773</u>
Cash flows from financing activities:			
Proceeds from public offerings of common stock, net of issuance costs	263,688	204,024	112,441
Proceeds from issuance of common stock, net	284,203	9,470	17,511
Proceeds from issuance of convertible senior notes, net	—	339,900	—
Proceeds from issuance of debt, net	129,214	—	93,909
Payments of debt extinguishment costs	—	(10,638)	(4,609)
Loan payments	—	(75,000)	(60,000)
Other	(4,112)	(2,985)	(2,100)
Net cash provided by financing activities	<u>672,993</u>	<u>464,771</u>	<u>157,152</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>(26,092)</u>	<u>39,408</u>	<u>100,705</u>
Cash, cash equivalents and restricted cash at beginning of period	<u>157,572</u>	<u>118,164</u>	<u>17,459</u>
Cash, cash equivalents and restricted cash at end of period	<u>\$ 131,480</u>	<u>\$ 157,572</u>	<u>\$ 118,164</u>
Supplemental cash flow information:			
Interest paid	\$ 12,130	\$ 4,731	\$ 6,231
Supplemental cash flow information of non-cash investing and financing activities:			
Equipment acquired through finance leases	\$ 4,463	\$ 1,892	\$ —
Purchases of property and equipment in accounts payable and accrued liabilities	\$ 1,869	\$ 2,422	\$ 510
Warrants issued pursuant to debt agreement	\$ 27,000	\$ —	\$ 383
Common stock issued for acquisitions	\$ 1,157,958	\$ 108,573	\$ 6,445
Consideration payable for acquisitions	\$ 940,829	\$ 21,449	\$ —
Operating lease assets obtained in exchange for lease obligations, net	\$ 14,058	\$ 4,261	\$ —

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Notes to Consolidated Financial Statements

1. Organization and description of business

Invitae Corporation ("Invitae," "the Company," "we," "us," and "our") was incorporated in the State of Delaware on January 13, 2010, as Locus Development, Inc. and we changed our name to Invitae Corporation in 2012. We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, personalized oncology, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets including four businesses in 2020, which expanded our suite of genome management offerings and established a broader entry into oncology therapy selection and personalized cancer monitoring.

In October 2020, we completed the acquisition of ArcherDX, Inc. ("ArcherDX"). ArcherDX is a genomics company democratizing precision oncology by offering a suite of products and services that are accurate, personal, actionable and easy to use in local settings, thereby empowering clinicians to control the sample, data, patient care and economics. ArcherDX's development platform, including its proprietary Anchored Multiplex PCR, ("AMP"), chemistry at the core, is enabling clinical tests and services that allow for therapy selection and cancer monitoring in community locations for the first time at scale. Invitae operates in one segment.

2. Summary of significant accounting policies

Principles of consolidation

Our consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. We base these estimates on current facts, historical and anticipated results, trends and various other assumptions that we believe are reasonable under the circumstances, including assumptions as to future events. Actual results could differ materially from those judgments, estimates and assumptions. We evaluate our estimates on an ongoing basis.

Significant estimates and assumptions made by management include the determination of:

- revenue recognition;
- the fair value of assets and liabilities associated with business combinations;
- the impairment assessment of goodwill and intangible assets;
- the valuation of our 2.00% convertible senior notes due 2024 issued in September 2019 ("Convertible Senior Notes");
- the recoverability of long-lived assets;
- our incremental borrowing rates used to calculate our lease balances;
- stock-based compensation expense and the fair value of awards and warrants issued; and
- income tax uncertainties.

Concentrations of credit risk and other risks and uncertainties

Financial instruments that potentially subject us to a concentration of credit risk consist of cash, cash equivalents, marketable securities and accounts receivable. Our cash and cash equivalents are held by financial institutions in the United States. Such deposits may exceed federally insured limits.

Significant customers are those that represent 10% or more of our total revenue for each year presented on the consolidated statements of operations. Our revenue from significant customers as a percentage of our total revenue was as follows:

	Year Ended December 31,		
	2020	2019	2018
Medicare	19 %	25 %	22 %

No customers represented more than 10% of accounts receivable as of December 31, 2020 or 2019.

Cash, cash equivalents, and restricted cash

We consider all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds, U.S. treasury notes and government agency securities.

Restricted cash consists primarily of money market funds that secure irrevocable standby letters of credit that serve as collateral for security deposits for our facility leases.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows (in thousands):

	December 31,	
	2020	2019
Cash and cash equivalents	\$ 124,794	\$ 151,389
Restricted cash	6,686	6,183
Total cash, cash equivalents and restricted cash	\$ 131,480	\$ 157,572

Marketable securities

All marketable securities have been classified as “available-for-sale” and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its marketable debt securities at the time of purchase and reevaluates such designation at each balance sheet date. Short-term marketable securities have maturities one year or less at the balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive loss. Realized gains and losses and impairments, if any, on available-for-sale securities are included in other expense, net. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in other income (expense), net.

For marketable securities in an unrealized loss position, we assess our intent to sell, or whether it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. If either of these criteria are met, the security’s amortized cost basis is written down to fair value through other income (expense), net.

Accounts receivable

We receive payment from patients, biopharmaceutical partners, third-party payers and other business-to-business customers. See Note 3, "Revenue, accounts receivable and deferred revenue" for further information.

Deferred revenue

We record a contract liability when cash payments are received or due in advance of our performance related to one or more performance obligations. See Note 3, "Revenue, accounts receivable and deferred revenue" for further information.

Inventory

Our inventory consists of raw materials, work in progress, and finished goods, which are stated at the lower of cost or net realizable value on a first-in, first-out basis. We periodically analyze our inventory levels and expiration dates, and write down inventory that has become obsolete, inventory that has a cost basis in excess of its net realizable value, and inventory in excess of expected sales requirements as cost of revenue. We record an allowance for obsolete inventory using an estimate based on historical trends and evaluation of near-term expirations.

Business combinations

We apply Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") 805, *Business Combinations*, which requires recognition of assets acquired, liabilities assumed, and contingent consideration at their fair value on the acquisition date with subsequent changes recognized in earnings; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination and expensed as incurred; requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset until completion or abandonment; and requires that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of provision for taxes.

We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. We base the estimated fair value of identifiable intangible assets acquired in a business combination on independent third-party valuations that use information and assumptions provided by our management, which consider our estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, estimated cost savings, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under ASC Topic 480, *Distinguishing Liabilities from Equity*, we recognize a liability equal to the fair value of the contingent payments we expect to make as of the acquisition date. We remeasure this liability each reporting period and record changes in the fair value as general and administrative expense.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in our operating results from the date of acquisition.

Intangible assets

Amortizable intangible assets include trade names, non-compete agreements, patent licensing agreements, favorable leases, developed technology, customer relationships, and rights to develop new technology acquired as part of business combinations. Customer relationships acquired through our business combinations in 2017 are amortized on an accelerated basis, utilizing free cash flows, over periods ranging from five to 12 years. All other intangible assets subject to amortization are amortized using the straight-line method over their estimated useful lives ranging from two to 15 years. All intangible assets subject to amortization are reviewed for impairment in accordance with ASC 360, *Property, Plant and Equipment*.

Goodwill

In accordance with ASC 350, *Intangibles-Goodwill and Other* ("ASC 350"), our goodwill is not amortized but is tested for impairment on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. Under ASC 350, we perform annual impairment reviews of our goodwill balance during the fourth fiscal quarter or more frequently if business factors indicate. In testing for impairment, we compare the fair value of our reporting unit to its carrying value including the goodwill of that unit. If the carrying value, including goodwill, exceeds the reporting unit's fair value, we will recognize an impairment loss for the amount by which the carrying amount exceeds the reporting unit's fair value. The loss recognized cannot exceed the total amount of goodwill allocated to that reporting unit. We did not incur any goodwill impairment losses in any of the periods presented.

In-process research and development

Intangible assets related to in-process research and development costs (“IPR&D”) are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. During this period, the assets will not be amortized but will be tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts.

During the fourth quarter and if business factors indicate more frequently, we perform an assessment of the qualitative factors affecting the fair value of our IPR&D projects. If the fair value exceeds the carrying value, there is no impairment. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of an asset to its carrying value, without consideration of any recoverability test. We have not identified any such impairment losses to date.

Leases

Under ASC 842, *Leases*, we determine if an arrangement is a lease at inception. Operating leases are included in operating lease assets and operating lease obligations in our consolidated balance sheets. Finance leases are included in other assets and finance lease obligations in our consolidated balance sheets.

Lease assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at commencement based on the present value of lease payments over the lease term. We generally use our incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments. The operating lease asset also includes any lease payments made and is adjusted for lease incentives. Our lease terms may include options to extend or terminate the lease which are recognized when it is reasonably certain that we will exercise that option. Leases with terms of 12 months or less are not recorded on our balance sheet. Lease expense is recognized on a straight-line basis over the lease terms, or in some cases, the useful life of the underlying asset. We account for the lease and non-lease components as a single lease component.

Property and equipment, net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and seven years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

The estimated useful lives of property and equipment are as follows:

Furniture and fixtures	7 years
Automobiles	7 years
Manufacturing and Laboratory equipment	5 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	Shorter of lease term or estimated useful life

Long-lived assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows or other appropriate measures of fair value. There were no long-lived asset impairment losses recorded for any period presented.

Fair value of financial instruments

Our financial instruments consist principally of cash and cash equivalents, marketable securities, accounts payable, accrued liabilities, finance leases, and liabilities associated with business combinations. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued and other current liabilities approximate their current fair value due to the relatively short-term nature of these accounts. Based on borrowing rates available to us, the carrying value of finance leases approximate their fair values. Liabilities associated with business combinations are recorded at their estimated fair value.

Revenue recognition

We recognize revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration it expects to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers. We utilize the following practical expedients and exemptions:

- Costs to obtain or fulfill a contract are expensed when incurred because the amortization period would have been one year or less, and
- No adjustments to promised consideration were made for financing as we expect, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

Test revenue

Test revenue is comprised of testing services and sales of distributed precision oncology products.

The majority of our test revenue is generated from genetic testing, in addition to somatic testing for therapy selection and personalized cancer monitoring. These testing services provide analysis and associated interpretation of the sequencing of parts of the genome. Test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with biopharmaceutical partners, other business-to-business customers (e.g., hospitals, clinics, medical centers) and insurance companies that include pricing provisions under which such tests are billed. Billing terms are generally net 30 to 60 days.

While the transaction price of diagnostic tests is originally established either via contract or pursuant to our standard list price, we often provide concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which we will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur. Making these estimates requires significant judgments based upon such factors as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. These judgments are reviewed each reporting period and updated as necessary.

We look to transfer of control in assessing timing of recognition of revenue in connection with each performance obligation. In general, revenue in connection with the service portion of our diagnostic tests is recognized upon delivery of the underlying clinical report or when the report is made available on our web portal. Outstanding performance obligations pertaining to orders received but for which the underlying report has not been issued are generally satisfied within a 30-day period.

We also generate test revenue through the sale of our precision oncology products, which is comprised primarily of sales of our distributed research use only ("RUO") and in vitro diagnostics ("IVD") products for therapy selection. We recognize revenue on these sales once shipment has occurred. Product sales are recorded net of discounts and other deductions. Billing terms are generally net 30 days.

Shipping and handling fees billed to customers are recorded as revenue on the consolidated statements of operations. The associated shipping and handling costs are recorded as cost of revenue.

Other revenue

Other revenue is primarily generated from pharma development services provided to biopharmaceutical companies related to companion diagnostic development as well as through collaboration agreements and genome network contracts.

Contracts for companion diagnostic development consist primarily of milestone-based payments along with annual fees and marked-up pass-through costs. The arrangements are treated as short-term contracts for revenue recognition purposes because they allow termination of the agreements by the customers with 30 to 120 days' written notice without a termination penalty. Upon termination, customers are required to pay for the proportion of services provided under milestones that were in progress. We recognize revenue in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenue over time based on the progress made toward achieving the performance obligation, utilizing both input or output methods, depending on the performance obligation, including labor hours expended, tests processed, or time elapsed, that measure our progress toward the achievement of the milestone.

We also enter into collaboration and genome network contracts. Collaboration agreements provide customers with diagnostic testing and related data aggregation reporting services that are provided over the contract term. Collaboration revenue is recognized as the data and reporting services are delivered to the customer. Genome network offerings consist of subscription services related to a proprietary software platform designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis and treatment of hereditary disease. Such services are recognized on a straight-line basis over the subscription periods. Amounts due under collaboration and genome network agreements are typically billable on net 30-day terms.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering our genetic offerings and includes expenses for personnel-related costs including stock-based compensation, materials and supplies, royalties, regulatory fees, commercialization fees, equipment and infrastructure expenses associated with testing and allocated overhead including rent, equipment depreciation, information technology costs, amortization of acquired intangibles and utilities.

License Agreements

We have entered and may continue to enter into license agreements to access and utilize certain technology. We evaluate if the license agreement results in the acquisition of an asset or a business and then determine if the acquired asset has the ability to generate revenues or is subject to regulatory approval. When regulatory approval is not required, we record the license as an asset and amortize it over the estimated economic life. When regulatory approval is required, we record the amount paid as a research and development expense.

Income taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Significant judgment is required in determining the net valuation allowance which includes our evaluation of all available evidence including past operating results, estimates on future taxable income and acquisition-related tax assets and liabilities.

We historically established a full valuation allowance against our deferred tax assets due to the uncertainty surrounding realization of such assets. In 2020, we released approximately \$112.1 million of our valuation allowance to account for acquired intangibles that support the future realization of some of our deferred tax assets. Due to the overall increase of deferred tax assets, our valuation allowance has also increased from the prior year.

Stock-based compensation

We measure stock-based payment awards made to employees and directors based on the estimated fair values of the awards and recognize the compensation expense over the requisite service period. We use the Black-Scholes option-pricing model to estimate the fair value of stock option awards and employee stock purchase plan ("ESPP") purchases. The fair value of restricted stock unit ("RSU") awards with time-based vesting terms is based on the grant date share price. We grant performance-based restricted stock unit ("PRSU") awards to certain employees which vest upon the achievement of certain performance conditions, subject to the employees' continued service relationship with us. The probability of vesting is assessed at each reporting period and compensation cost is adjusted based on this probability assessment. We recognize such compensation expense on an accelerated vesting method.

Stock-based compensation expense for awards without a performance condition is recognized using the straight-line method. Stock-based compensation expense is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, our stock-based compensation is reduced for estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

We account for stock issued in connection with business combinations based on the fair value on the date of issuance.

Advertising

Advertising expenses are expensed as incurred. We incurred advertising expenses of \$11.4 million, \$9.9 million and \$0.6 million during the years ended December 31, 2020, 2019 and 2018, respectively.

Comprehensive loss

Comprehensive loss is composed of two components: net loss and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' equity, but are excluded from net loss. Our other comprehensive income (loss) consists of unrealized gains or losses on investments in available-for-sale securities.

Net loss per share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury stock method. Potentially dilutive securities, consisting of preferred stock, options to purchase common stock, common stock warrants, shares of common stock pursuant to ESPP, common stock issuable in connection with our Convertible Senior Notes, RSUs and PRSUs, are considered to be common stock equivalents and were excluded from the calculation of diluted net loss per share because their effect would be antidilutive for all periods presented.

Prior period reclassifications

We have reclassified certain amounts in prior periods to conform with current presentation.

Immaterial correction of an error

We determined the historical classification of certain acquisition-related obligations as equity and the subsequent measurement of such obligations was inappropriate and instead should have been classified as liabilities and subsequently measured at fair value with changes recognized in other expense, net during the year ended December 31, 2020. We determined that the impact of the error to previously issued consolidated financial statements was not material and have corrected the immaterial error in the current period financial statements. The impact of this correction was an increase to other long-term liabilities of \$10.1 million, a corresponding decrease to additional paid-in capital of \$10.4 million and an increase to other income, net of \$0.3 million.

Recent accounting pronouncements

We evaluate all Accounting Standards Updates ("ASUs") issued by the Financial Accounting Standards Board ("FASB") for consideration of their applicability. ASUs not included in the disclosures in this report were assessed and determined to be either not applicable or are not expected to have a material impact on our consolidated financial statements.

Recently issued accounting pronouncements not yet adopted

In August 2020, the FASB issued ASU No. 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for certain convertible instruments, amends the guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. This new standard is effective for our interim and annual periods beginning January 1, 2022, and earlier adoption is permitted. We may elect to apply the amendments on a retrospective or modified retrospective basis. We are currently evaluating the impact of the adoption of this standard on our consolidated financial statements.

Recently adopted accounting pronouncements

In June 2016, FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326), which requires measurement and recognition of expected credit losses for financial assets. This guidance became effective for us beginning in the first quarter of 2020 and was adopted using a modified retrospective approach, with certain exceptions. The adoption of Topic 326 did not have a material impact on our consolidated financial statements as credit losses are not expected to be significant.

As part of our adoption of Topic 326, we assess our accounts receivables for expected credit losses at each reporting period by disaggregating by payer type and further by portfolios of customers with similar characteristics, such as customer type and geographic location. We then review each portfolio for expected credit losses based on historical payment trends as well as forward looking data and current economic trends. If a credit loss is determined, we record a reduction to our accounts receivable balance with a corresponding general and administrative expense.

In accordance with Topic 326, we no longer evaluate whether our available-for-sale debt securities in an unrealized loss position are other than temporarily impaired. Instead, we assess whether such unrealized loss positions are credit-related. Our expected loss allowance methodology for these securities is developed by reviewing the extent of the unrealized loss, the issuers' credit ratings and any changes in those ratings, as well as reviewing current and future economic market conditions and the issuers' current status and financial condition. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income (expense), net. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive income (loss).

On January 1, 2019, we adopted the provisions of ASC Topic 842, *Leases*, using the modified retrospective approach in accordance with Topic 842. Adoption of Topic 842 had a material impact on our consolidated balance sheets, but did not have an impact on our consolidated statements of operations. We elected the package of practical expedients permitted under the transition guidance which, among other things, allowed us to carry forward the historical classification of leases in place as of January 1, 2019. We did not identify any material embedded leases with the adoption of Topic 842 and therefore the implementation of Topic 842 primarily focused on the treatment of our previously identified leases.

Prior period amounts were not adjusted and continue to be reported in accordance with our historic accounting under previous lease guidance, ASC 840, *Leases*. Under ASC 840, we rented facilities under operating lease agreements and recognized related rent expense on a straight-line basis over the term of the applicable lease agreement. Some of the lease agreements contained rent holidays, scheduled rent increases, lease incentives, and renewal options. Rent holidays and scheduled rent increases were included in the determination of rent expense recorded over the lease term. Lease incentives were recognized as a reduction of rent expense on a straight-line basis over the term of the lease. Renewals were not assumed in the determination of the lease term unless they were deemed to be reasonably assured at the inception of the lease. We recognized rent expense beginning on the date we obtained the legal right to use and control the leased space.

3. Revenue, accounts receivable and deferred revenue

Test revenue is generated from sales of diagnostic tests and precision oncology products to four groups of customers: biopharmaceutical partners; patients who pay directly; patients' insurance carriers; and other business-to-business customers (e.g., hospitals, clinics, medical centers). Test revenue is generated in two ways: through a centralized lab and decentralized through the shipment of reactions to biopharma partners and other business-to-business customers. We refer to the set of reagents needed to perform a next-generation sequencing test as a "reaction." Amounts billed and collected, and the timing of collections, vary based on the type of payer. Other revenue consists principally of revenue recognized under contracts for pharma development services and other collaboration and genome network agreements and is accounted for under the provisions provided in ASC 606, *Revenue from Contracts with Customers*.

Our revenue as disaggregated by payer category and revenue subtype is as follows (in thousands):

	Patient		Biopharma partner	Other business-to-business	Year Ended December 31, 2020
	Insurance	Direct			
Test revenue:					
Centralized	\$ 181,026	\$ 23,972	\$ 26,228	\$ 32,736	\$ 263,962
Decentralized	—	—	837	7,511	8,348
Total test revenue	181,026	23,972	27,065	40,247	272,310
Other revenue	—	—	4,488	2,800	7,288
Total revenue	\$ 181,026	\$ 23,972	\$ 31,553	\$ 43,047	\$ 279,598

	Patient		Biopharma partner	Other business-to-business	Year Ended December 31, 2019
	Insurance	Direct			
Test revenue:					
Centralized	\$ 153,827	\$ 17,597	\$ 10,876	\$ 30,173	\$ 212,473
Total test revenue	153,827	17,597	10,876	30,173	212,473
Other revenue	—	—	2,077	2,274	4,351
Total revenue	\$ 153,827	\$ 17,597	\$ 12,953	\$ 32,447	\$ 216,824

	Patient		Biopharma partner	Other business-to-business	Year Ended December 31, 2018
	Insurance	Direct			
Test revenue:					
Centralized	\$ 96,352	\$ 13,589	\$ 6,231	\$ 28,388	\$ 144,560
Total test revenue	96,352	13,589	6,231	28,388	144,560
Other revenue	—	—	1,565	1,574	3,139
Total revenue	\$ 96,352	\$ 13,589	\$ 7,796	\$ 29,962	\$ 147,699

We recognize revenue related to billings based on estimates of the amount that will ultimately be realized. Cash collections for certain tests delivered may differ from rates originally estimated. As a result of new information, we update our estimate quarterly of the amounts to be recognized for previously delivered tests which resulted in the following increases to revenue and decreases to our loss from operations and basic and diluted net loss per share (in millions, except per share amounts):

	Year Ended December 31,		
	2020	2019	2018
Revenue	\$ 4.4	\$ 4.1	\$ 4.5
Loss from operations	\$ (4.4)	\$ (4.1)	\$ (4.5)
Net loss per share, basic and diluted	\$ (0.03)	\$ (0.05)	\$ (0.07)

Impact of COVID-19

Our billable volumes decreased significantly in the second half of March 2020 as compared to the first few months of 2020 as a result of COVID-19 and related limitations and priorities across the healthcare system. Our daily test volumes have consistently increased from the low in March 2020, although we are currently still experiencing changes in product mix due to the impact of COVID-19. COVID-19 could have a material impact on our financial results for the foreseeable future, particularly on product mix and as a result, the revenue we recognize. We have reviewed and adjusted for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

Approximately 8% of our workforce as of March 31, 2020 was impacted by a reduction in force in April 2020 in an initiative to manage costs and cash burn that resulted in one-time costs in the second quarter of 2020 of \$3.8 million. In addition, effective May 2020, we have reduced the salaries of our named executive officers by approximately 20%, which reductions ceased as of January 2021.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was signed into law which was a stimulus bill intended to bolster the economy, among other things, and provide assistance to qualifying businesses and individuals. The CARES Act included an infusion of funds into the healthcare system, and in April 2020, we received \$3.8 million as a part of this initiative. This payment was recognized as other income (expense), net in our consolidated statement of operations during the year ended December 31, 2020. We also received \$2.3 million in January 2021 which we recognized as other income (expense), net during the three months ended March 31, 2021. At this time, we are not certain of the availability, extent or impact of any future relief provided under the CARES Act.

Accounts receivable

The majority of our accounts receivable represents amounts billed to pharmaceutical partners and other business-to-business customers for test and other revenue recognized, and estimated amounts to be collected from third-party insurance payers for genetic testing revenue recognized. Also included are amounts due under the terms of collaboration and genome network agreements for diagnostic testing and data aggregation reporting services provided and proprietary platform access rights transferred.

We also record unbilled revenue for revenue recognized but yet to be billed for services provided to biopharmaceutical companies related to companion diagnostic development. The amount is a contract receivable and is included in accounts receivable on the consolidated balance sheets; unbilled revenue was \$4.3 million and nil as of December 31, 2020 and 2019, respectively.

Deferred revenue

We record a contract liability when cash payments are received or due in advance of our performance related to one or more performance obligations. The deferred revenue balance primarily consists of advanced billings for pharma development services, including billings at the initiation of a performance-based milestones, and recognized as revenue in the applicable future period when the revenue is earned. Also included are prepayments related to our consumer direct channel. We recognized revenue of \$1.4 million from deferred revenue for the year ended as of December 31, 2020. In addition, we recognized deferred revenue of \$4.8 million upon the acquisition of ArcherDX in October 2020, \$2.0 million of which was recognized as revenue during the year ended December 31, 2020.

4. Business combinations

Singular Bio

In June 2019, we acquired 100% of the fully diluted equity of Singular Bio, a privately held company developing single molecule detection technology, for approximately \$57.3 million, comprised of \$53.9 million in the form of 2.5 million shares of our common stock and the remainder in cash.

We granted approximately \$90.0 million of restricted stock units ("RSU") under our 2015 Stock Incentive Plan as inducement awards to new employees who joined Invitae in connection with our acquisition of Singular Bio. \$45.0 million of the RSUs are time-based and vested in three equal installments in December 2019, June 2020, and December 2020, subject to the employee's continued service with us ("Time-based RSUs") and \$45.0 million of the RSUs are performance-based RSUs ("PRSU") that vest upon the achievement of certain performance conditions. Since the number of awards granted is based on a 30-day volume weighted-average share price with a fixed dollar value, these Time-based RSUs and PRSUs are liability-classified and the fair value is estimated at each reporting period based on the number of shares that are expected to be issued at each reporting date and our closing stock price, which combined are categorized as Level 3 inputs. Therefore, fair value of the RSUs and PRSUs and the number of shares to be issued will not be fixed until the awards vest.

During the years ended December 31, 2020 and 2019, we recorded research and development stock-based compensation expense of \$29.1 million and \$14.7 million, respectively, related to the Time-based RSUs, and \$19.4 million and \$24.4 million, respectively, related to the PRSUs based on our evaluations of the probability of achieving performance conditions. As of December 31, 2020, the Time-based RSUs and PRSUs had a total fair value of \$43.9 million and \$43.8 million, respectively, based on a total estimated issuance of 3.5 million shares and expectation of the achievement of the performance conditions. As of December 31, 2020, 2.0 million of the Time-based RSUs and 1.2 million of the PRSUs had vested with a total fair value of \$75.0 million which was recorded in common stock issued or issuable pursuant to acquisitions in the consolidated statements of stockholders' equity.

Jungla

In July 2019, we acquired 100% of the equity interest of Jungla, a privately held company developing a platform for molecular evidence testing in genes, for approximately \$59.0 million, comprised of \$44.9 million in the form of shares of our common stock and the remainder in cash.

We may be required to pay contingent consideration based on achievement of post-closing development milestones. As of the acquisition date, the fair value of this contingent consideration was \$10.7 million including cash and common stock. These milestones are expected to be completed within two years of the date of acquisition, two of which were completed during the year ended December 31, 2020. The material factors that may impact the fair value of the contingent consideration, and therefore, this liability, are the probabilities and timing of achieving the related milestones and the discount rate we used to estimate the fair value, which are Level 3 inputs not supported by market activity. Significant changes in any of the probabilities of success would result in a significant change in the fair value, which will be estimated at each reporting date with changes reflected as a general and administrative expense. As of December 31, 2020, the fair value of this contingent consideration was \$7.1 million.

Upon acquisition, we had a stock payable liability related to our acquisition of Jungla which represents the hold-back obligation to issue 0.2 million shares subject to indemnification claims that may arise. This liability was adjusted at each reporting period based on the fair value of our common stock, which is a Level 3 input, with the change recorded in other income (expense), net. During July 2020, the hold-back shares were remitted in full to the former owners of Jungla.

Clear Genetics

In November 2019, we acquired 100% of the equity interest of Clear Genetics, a developer of software for providing genetic services at scale, for approximately \$50.1 million. Of the cash and stock purchase price consideration issued, \$0.2 million of cash and approximately 0.4 million shares of our common stock were subject to a 12-month hold back to satisfy indemnification obligations that were released during the year ended December 31, 2020.

Diploid

In March 2020, we acquired 100% of the equity interest of Diploid, a developer of artificial intelligence software capable of diagnosing genetic disorders using sequencing data and patient information, for approximately \$82.3 million in cash and shares of our common stock. Of the stock purchase price consideration issued, approximately 0.4 million shares are subject to a hold-back to satisfy indemnification obligations that may arise. We included the financial results of Diploid in our consolidated financial statements from the acquisition date, which were not material for the year ended December 31, 2020.

The following table summarizes the purchase price recorded as a part of the acquisition of Diploid (in thousands):

	Purchase Price	
Cash transferred	\$	32,323
Hold-back consideration - common stock		7,538
Common stock transferred		42,453
Total	\$	82,314

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by us. While we believe that our estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed through our acquisition of Diploid at the date of acquisition (in thousands):

Cash	\$	124
Accounts receivable		26
Developed technology		41,789
Total identifiable assets acquired		41,939
Accounts payable		(30)
Deferred tax liability		(10,250)
Net identifiable assets acquired		31,659
Goodwill		50,655
Total purchase price	\$	82,314

Based on the guidance provided in ASC 805, *Business Combinations*, we accounted for the acquisition of Diploid as a business combination and determined that 1) Diploid was a business which combines inputs and processes to create outputs, and 2) substantially all of the fair value of gross assets acquired was not concentrated in a single identifiable asset or group of similar identifiable assets.

Our purchase price allocation for the acquisition is preliminary and subject to revision as additional information about fair value of assets and liabilities becomes available, primarily related to our deferred tax liability assumed in connection with the acquisition. Additional information that existed as of the acquisition date but at the time was unknown to us may become known to us during the remainder of the measurement period, a period not to exceed 12 months from the acquisition date.

We measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill. The intangible asset acquired is developed technology related to Diploid's artificial intelligence technology platform. The fair value of the developed technology was estimated using an income approach with an estimated useful life of nine years. As of the acquisition date, we recorded a stock payable liability of \$7.5 million to represent the hold-back obligation to issue 0.4 million shares subject to indemnification claims that may arise. This liability is adjusted at each reporting period based on the fair value of our common stock, which is a Level 3 input. As of December 31, 2020, the value of this liability was \$17.7 million with the change recorded in other income (expense), net.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Diploid resulted in the recognition of \$50.7 million of goodwill which we believe relates primarily to expansion of the acquired technology to apply to new areas of genetic testing. The goodwill created as a result of the acquisition of Diploid is not deductible for the foreign local tax purposes.

In June 2020, we granted 0.2 million RSUs with a fair value of \$3.6 million under our 2015 Stock Incentive Plan as inducement awards in connection with our acquisition of Diploid. These RSUs vest in two equal installments, in April 2021 and April 2022. The value of the awards was recognized as research and development stock-based compensation upon grant in June 2020 as there were no ongoing obligations required by the award recipients.

Genelex and YouScript

In April 2020, we acquired 100% of the equity interest of Genelex and YouScript to bring pharmacogenetic testing and integrated clinical decision support to Invitae. We acquired Genelex for approximately \$13.2 million,

primarily in shares of our common stock. Of the stock purchase price consideration issued, approximately 0.1 million shares are subject to a hold-back to satisfy indemnification obligations that may arise. We acquired YouScript for approximately \$52.7 million, including cash consideration of \$24.5 million and the remaining in shares of our common stock. Of the purchase price consideration for YouScript, approximately \$1.4 million and 0.5 million shares of our common stock are subject to a hold-back to satisfy indemnification obligations that may arise. We included the financial results of Genelex and YouScript in our consolidated financial statements from the acquisition date, which were not material for the year ended December 31, 2020. We recorded \$1.7 million of transaction costs related to the acquisition of Genelex and YouScript as general and administrative expense during the year ended December 31, 2020.

We may be required to pay contingent consideration in the form of additional shares of our common stock in connection with the acquisition of Genelex if, within a specified period following the closing, we achieve a certain product milestone, in which case we would issue shares of our common stock with a value equal to a portion of the gross revenues actually received by us for a pharmacogenetic product reimbursed through certain payers during an earn-out period of up to four years. As of the acquisition date, the fair value of this contingent consideration was \$2.0 million in the form of shares of our common stock. The material factors that may impact the fair value of the contingent consideration, and therefore, this liability, are the probabilities and timing of achieving the related milestone, the estimated revenues achieved for a pharmacogenetic product and the discount rate we used to estimate the fair value, which are Level 3 inputs not supported by market activity. Significant changes in any of the probabilities of success would result in a significant change in the fair value, which is estimated at each reporting date with changes reflected as general and administrative expense. As of December 31, 2020, the fair value of this contingent consideration was \$1.2 million.

The following table summarizes the purchase prices recorded as a part of the acquisition of Genelex and YouScript (in thousands):

	Genelex	YouScript	Total
Cash transferred	\$ 972	\$ 24,462	\$ 25,434
Hold-back consideration - cash	—	1,385	1,385
Hold-back consideration - common stock	781	5,392	6,173
Contingent consideration	1,994	—	1,994
Common stock transferred	9,463	21,464	30,927
Total	\$ 13,210	\$ 52,703	\$ 65,913

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by us. While we believe that our estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed through our acquisitions of Genelex and YouScript at the date of acquisition (in thousands):

	Genelex	YouScript	Total
Cash	\$ 33	\$ 24	\$ 57
Accounts receivable	221	56	277
Prepaid expenses and other current assets	—	70	70
Operating lease assets	—	355	355
Developed technology	9,209	25,716	34,925
Total identifiable assets acquired	9,463	26,221	35,684
Current liabilities	(320)	(481)	(801)
Deferred tax liability	—	(2,600)	(2,600)
Other long-term liabilities	—	(163)	(163)
Net identifiable assets acquired	9,143	22,977	32,120
Goodwill	4,067	29,726	33,793
Total purchase price	\$ 13,210	\$ 52,703	\$ 65,913

Based on the guidance provided in ASC 805, *Business Combinations*, we accounted for the acquisitions of Genelex and YouScript as business combinations and determined that 1) Genelex and YouScript were businesses which combine inputs and processes to create outputs, and 2) substantially all of the fair value of gross assets acquired were not concentrated in a single identifiable asset or group of similar identifiable assets.

Our purchase price allocation for the acquisitions is preliminary and subject to revision as additional information about fair value of assets and liabilities becomes available, primarily related to our deferred tax liability assumed. Additional information that existed as of the acquisition date but at the time was unknown to us may become known to us during the remainder of the measurement period, a period not to exceed 12 months from the acquisition date.

We measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill. The intangible assets acquired are the developed technologies related to Genelex's and YouScript's technology platforms. The fair value of the developed technologies were estimated using an income approach with an estimated useful life of eight years. As of the acquisition date, we recorded stock payable liabilities of \$6.2 million to represent the hold-back obligation to issue shares subject to indemnification claims that may arise. These liabilities are adjusted at each reporting period based on the fair value of our common stock, which is a Level 3 input. As of December 31, 2020, the value of this liability was \$21.6 million with the change recorded in other income (expense), net.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisitions of Genelex and YouScript resulted in the recognition of \$33.8 million of goodwill which we believe relates primarily to future functionality and expansion of the acquired technologies. Of the goodwill recognized, \$29.7 million related to the YouScript acquisition is not deductible for tax purposes.

ArcherDX

In June 2020, we entered into a definitive agreement with ArcherDX, a genomics analysis company democratizing precision oncology, and in October 2020, the closing conditions were met and the transaction was consummated. Under the terms of the agreement, we acquired 100% of the equity interest of ArcherDX for \$2.3 billion, comprised of \$2.0 billion in the form of our common stock, \$2.0 million in liabilities, and the remainder in cash. We incurred \$20.9 million of transaction costs related to the acquisition of ArcherDX which we recorded as general and administrative expense during the year ended December 31, 2020.

We may be required to pay contingent consideration based on achievement of post-closing development and revenue milestones. As of the acquisition date, the total fair value of the contingent consideration was \$945.2 million, \$933.6 million of which was included in the purchase price and \$11.6 million recognized as non-recurring post-combination compensation expense. Of this \$933.6 million, \$925.1 million would be in the form of shares of our common stock which will be priced at the time of the milestone achievement, and the remainder in cash. The milestones are expected to be completed within approximately two years from the date of the acquisition, with one of them being achieved during November 2020 which resulted in the issuance of 5.0 million shares of our common stock and a cash payment of \$1.9 million. This milestone achievement subsequent to the acquisition date resulted in the recognition of \$40.6 million general and administrative expense. The material factors that may impact the fair value of the contingent consideration, and therefore the liability, are (i) the estimated number of shares issued, (ii) the volatility assumptions of our common stock used in the Monte Carlo simulation, (iii) the probabilities and timing of achievement of milestones and (iv) discount rates, all of which are Level 3 inputs not supported by market activity. Significant changes in any of these inputs may result in a significant change in fair value, which is estimated at each reporting date with changes reflected as general and administrative expense. As of December 31, 2020, the fair value of the contingent consideration representing the remaining milestones was \$788.3 million.

In connection with the acquisition, all of ArcherDX's equity awards outstanding and unvested prior to the acquisition became fully vested per the terms of the agreement. The acceleration of vesting required us to allocate the fair value of the equity attributable to the pre-combination service to the purchase price and the remaining amount of \$125.8 million, inclusive of \$11.6 million in contingent consideration, to non-recurring post-combination expense which we recognized as general and administrative expense during the year ended December 31, 2020.

We included the financial results of ArcherDX in our consolidated financial statements from the acquisition date, which contributed \$16.2 million and \$24.8 million of revenue and net loss, respectively, during the year ended December 31, 2020.

The following table summarizes the purchase price and post-combination expense recorded as a part of the acquisition of ArcherDX (in millions):

	<u>Purchase Price</u>	<u>Post-combination Expense</u>
Cash transferred	\$ 335.3	\$ 22.5
Contingent consideration and liabilities incurred	935.6	12.3
Common stock transferred	1,060.6	91.0
Total	<u>\$ 2,331.5</u>	<u>\$ 125.8</u>

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by us. While we believe that our estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed through our acquisition of ArcherDX at the date of acquisition (in millions):

Cash	\$	9.1
Accounts receivable		12.1
Inventory		17.6
Prepaid expenses and other current assets		6.8
Property and equipment, net		17.1
Operating lease assets		7.9
Intangible assets		803.8
Other assets		0.7
Total identifiable assets acquired		875.1
Accounts payable		(4.6)
Accrued liabilities		(18.0)
Operating lease obligations		(1.3)
Operating lease obligations, net of current portion		(7.4)
Deferred tax liability		(151.1)
Other liabilities		(13.6)
Net identifiable assets acquired		679.1
Goodwill		1,652.4
Total purchase price	\$	2,331.5

Based on the guidance provided in ASC 805, *Business Combinations*, we accounted for the acquisition of ArcherDX as a business combination and determined that 1) ArcherDX was a business which combines inputs and processes to create outputs, and 2) substantially all of the fair value of gross assets acquired was not concentrated in a single identifiable asset or group of similar identifiable assets.

Our purchase price allocation for the acquisition is preliminary and subject to revision as additional information about fair value of assets and liabilities becomes available, primarily related to our deferred tax liability assumed in connection with the acquisition. Additional information that existed as of the acquisition date but at the time was unknown to us may become known to us during the remainder of the measurement period, a period not to exceed 12 months from the acquisition date.

We measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill. The intangible assets acquired are the developed technology related to ArcherDX's artificial intelligence technology platform, IPR&D for its STRATAFIDE and PCM products, ArcherDX's customer relationships in place at the time of acquisition, and the ArcherDX tradename. We also acquired the right to develop new technology through an existing agreement for the development and commercialization of sequencing-based companion diagnostics between ArcherDX and a vendor. The fair value of our intangible assets acquired as of the acquisition date and the method used to value these assets as well as the estimated economic lives for amortizable intangible assets were as follows (in millions, except estimated useful life which is in years):

	Fair value	Estimated useful life	Valuation method	Amortization expense
Customer relationships	\$ 17.3	12.0	With-and-without	Selling and marketing
Tradename	21.1	12.0	Relief from royalty	Selling and marketing
Developed technology	233.6	12.0	Multi-period excess earnings	Cost of revenue
Right to develop new technology	19.4	15.0	Cost approach	Research and development
In-process research and development	512.4	n/a	Multi-period excess earnings	Not applicable
Total	\$ 803.8			

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of ArcherDX resulted in the recognition of \$1.7 billion of goodwill which we believe relates primarily to the anticipated benefits of synergies created through the acquisition and assembled workforce. The acquisition of ArcherDX advances our objectives to create a comprehensive offering that provides testing services for disease risk, therapy selection and personalized cancer monitoring to enable precision approaches to cancer treatment. Goodwill created as a result of the acquisition of ArcherDX is not deductible for tax purposes.

We recorded an income tax benefit of \$109.5 million in the three months ended December 31, 2020 due to net deferred tax liabilities assumed in connection with our acquisition of ArcherDX which provided a future source of income to support the realization of our deferred tax assets and resulted in a partial release of our valuation allowance.

In connection with the acquisition, we granted inducement awards of Invitae common stock to new employees who joined Invitae in connection with our acquisition of ArcherDX with an estimated fair value of \$112.2 million, net of estimated forfeitures. These awards vest upon the achievement of the contingent consideration milestones discussed above and are subject to the employee's continued service with us, unless terminated without cause in which case vesting is only dependent on milestone achievement. As the number of shares that are expected to be issued are fixed, the awards are equity-classified. During the year ended December 31, 2020, we recorded \$41.2 million in stock-based compensation expense based on our probability of milestone achievement. Included in the stock-based compensation expense is \$2.1 million related to the acceleration of stock-based compensation expense due to the termination of an employee without cause whereby the employee's continued service is not required.

Pro forma financial information (unaudited)

The audited pro forma financial information in the table below summarizes the combined results of operations for Invitae and ArcherDX as though the companies had been combined as of January 1, 2019. The pro forma amounts have been adjusted for:

- transaction expenses incurred by ArcherDX and us,
- depreciation expense resulting from the fair value of the acquired property and equipment,
- amortization expense resulting from the acquired intangible assets,
- the elimination of historical interest expense incurred by ArcherDX on its debt and debt-like items and the incurrence of interest expense related to the issuance of debt in connection with the acquisition,
- lease expense resulting from the step-up in the operating lease obligation and operating lease asset,
- nonrecurring post-combination expense,
- income tax benefits resulting from the deferred tax liabilities acquired, and
- the 26.3 million shares of our common stock issued upon the closing of the ArcherDX transaction.

The following unaudited pro forma financial information is for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved as if the acquisition had taken place as of January 1, 2019 (in thousands):

	Year Ended December 31,	
	2020	2019
Revenue	\$ 327,233	\$ 267,389
Net loss	(685,589)	(355,818)

5. Goodwill and intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows (in thousands):

Balance as of December 31, 2019	\$ 126,777
Goodwill acquired - Diploid	50,655
Goodwill acquired - Genelex	4,067
Goodwill acquired - YouScript	29,726
Goodwill acquired - ArcherDX	1,652,398
Balance as of December 31, 2020	<u>\$ 1,863,623</u>

Intangible assets

The following table presents details of our acquired intangible assets as of December 31, 2020 (in thousands):

	Cost	Accumulated Amortization	Net	Weighted-Average Useful Life (in Years)	Weighted-Average Estimated Remaining Useful Life (in Years)
Customer relationships	\$ 41,075	\$ (8,292)	\$ 32,783	10.8	8.8
Developed technology	397,563	(31,013)	366,550	10.6	10.0
Non-compete agreement	286	(229)	57	5.0	1.0
Tradename	21,085	(447)	20,638	12.0	11.8
Patent licensing agreement	496	(103)	393	15.0	11.9
Right to develop new technology	19,359	(323)	19,036	15.0	14.8
In-process research and development	542,388	—	542,388	n/a	n/a
	<u>\$ 1,022,252</u>	<u>\$ (40,407)</u>	<u>\$ 981,845</u>	10.9	10.2

Acquisition-related intangibles included in the above table are finite-lived, other than in-process research and development which has an indefinite life, and are carried at cost less accumulated amortization. Customer relationships related to our 2017 business combinations are being amortized on an accelerated basis, in proportion to estimated cash flows. All other finite-lived acquisition-related intangibles are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized. Amortization expense was \$26.6 million, \$7.7 million, and \$5.0 million for the years ended December 31, 2020, 2019 and 2018, respectively. Intangible assets are carried at cost less accumulated amortization. Amortization expense is recorded to cost of revenue, research and development, sales and marketing and general and administrative expense.

The following table summarizes our estimated future amortization expense of intangible assets with finite lives as of December 31, 2020 (in thousands):

2021	\$ 46,910
2022	45,401
2023	44,388
2024	44,110
2025	42,356
Thereafter	216,292
Total estimated future amortization expense	<u>\$ 439,457</u>

In December 2020, we entered into an agreement to acquire technology focused on informing clinical decisions for \$2.9 million. We accounted for this transaction as an asset acquisition of developed technology which will be amortized over eight years, initially to research and development expense. In connection with this transaction, we granted approximately \$6.2 million of RSUs under our 2015 Stock Incentive Plan as inducement awards to new employees who joined Invitae. These RSUs are time-based and vest in two equal installments in December 2021 and December 2022, subject to the employee's continued service with us. For \$5.4 million of these awards, the number of awards granted are based on the lower of the 20-day volume weighted-average share price prior to the vesting date and the date of close, both with a fixed dollar value, and therefore, these RSUs are liability-classified and the fair value is estimated at each reporting period based on the number of shares that are expected to be issued at each reporting date and our closing stock price, which combined are categorized as Level 3 inputs. Therefore, fair value of these RSUs and the number of shares to be issued will not be fixed until the awards vest. During the year ended December 31, 2020, we recorded research and development stock-based compensation expense of \$0.2 million related to the RSUs based on an estimated issuance of 0.1 million shares.

6. Balance sheet components

Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2020	2019
Raw materials	\$ 21,324	\$ 6,569
Work in progress	8,847	79
Finished goods	1,859	—
Total inventory	<u>\$ 32,030</u>	<u>\$ 6,648</u>

Property and equipment, net

Property and equipment consisted of the following (in thousands):

	December 31,	
	2020	2019
Leasehold improvements	\$ 26,516	\$ 18,352
Laboratory equipment	45,342	24,873
Computer equipment	10,939	5,995
Software	566	2,611
Furniture and fixtures	1,967	1,198
Automobiles	58	58
Construction-in-progress	12,061	10,795
Total property and equipment, gross	<u>97,449</u>	<u>63,882</u>
Accumulated depreciation and amortization	<u>(31,347)</u>	<u>(26,135)</u>
Total property and equipment, net	<u>\$ 66,102</u>	<u>\$ 37,747</u>

Depreciation expense was \$10.5 million, \$7.1 million and \$8.5 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2020	2019
Accrued compensation and related expenses	\$ 25,221	\$ 16,440
Deferred revenue	6,378	1,429
Compensation and other liabilities associated with business combinations	25,600	30,560
Other	28,859	16,385
Total accrued liabilities	<u>\$ 86,058</u>	<u>\$ 64,814</u>

Other long-term liabilities

Other long-term liabilities consisted of the following (in thousands):

	December 31,	
	2020	2019
Deferred revenue, non-current	1,380	—
Compensation and other liabilities associated with business combinations, non-current	825,976	8,000
Other	13,900	—
Total other long-term liabilities	<u>\$ 841,256</u>	<u>\$ 8,000</u>

7. Fair value measurements

Financial assets and liabilities are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The authoritative guidance establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques is summarized as follows:

Level 1—Observable inputs such as quoted prices (unadjusted) for identical instruments in active markets.

Level 2—Observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-derived valuations whose significant inputs are observable.

Level 3—Unobservable inputs that reflect the reporting entity's own assumptions.

The following tables set forth the fair value of our consolidated financial instruments that were measured at fair value on a recurring basis (in thousands):

	December 31, 2020						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	\$ 83,109	\$ —	\$ —	\$ 83,109	\$ 83,109	\$ —	\$ —
U.S. Treasury notes	164,894	7	(15)	164,886	164,886	—	—
U.S. government agency securities	64,291	9	—	64,300	—	64,300	—
Total financial assets	\$ 312,294	\$ 16	\$ (15)	\$ 312,295	\$ 247,995	\$ 64,300	\$ —
Financial liabilities:							
Stock payable liability				\$ 39,237	\$ —	\$ —	\$ 39,237
Contingent consideration				796,639	—	—	796,639
Total financial liabilities				\$ 835,876	\$ —	\$ —	\$ 835,876
					December 31, 2020		
Reported as:							
Cash equivalents					\$		76,423
Restricted cash							6,686
Marketable securities							229,186
Total cash equivalents, restricted cash, and marketable securities					\$		312,295
Accrued liabilities					\$		10,592
Other long-term liabilities					\$		825,284

December 31, 2019

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	\$ 39,396	\$ —	\$ —	\$ 39,396	\$ 39,396	\$ —	\$ —
Certificates of deposit	300	—	—	300	—	300	—
U.S. Treasury notes	150,627	—	(15)	150,612	150,612	—	—
U.S. government agency securities	193,302	6	—	193,308	—	193,308	—
Total financial assets	<u>\$ 383,625</u>	<u>\$ 6</u>	<u>\$ (15)</u>	<u>\$ 383,616</u>	<u>\$ 190,008</u>	<u>\$ 193,608</u>	<u>\$ —</u>
Financial liabilities:							
Contingent consideration				\$ 11,300	\$ —	\$ —	\$ 11,300
Total financial liabilities				<u>\$ 11,300</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 11,300</u>

	December 31, 2019
Reported as:	
Cash equivalents	\$ 136,997
Restricted cash	6,183
Marketable securities	240,436
Total cash equivalents, restricted cash, and marketable securities	<u>\$ 383,616</u>
Accrued liabilities	<u>\$ 3,300</u>
Other long-term liabilities	<u>\$ 8,000</u>

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. The total fair value of investments with unrealized losses at December 31, 2020 was \$109.3 million. None of the available-for-sale securities held as of December 31, 2020 have been in an unrealized loss position for more than one year. At December 31, 2020, the remaining contractual maturities of available-for-sale securities ranged from one to nine months. Interest income generated from our investments was \$4.0 million and \$5.2 million during the years ended December 31, 2020 and 2019, respectively.

Our certificates of deposit and debt securities of U.S. government agency entities are classified as Level 2 as they are valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to benchmark yields, interest rate curves, reported trades, broker/dealer quotes and reference data.

Stock payable liabilities relate to certain indemnification hold-backs resulting from business combinations that are settled in shares of our common stock. We elected to account for these liabilities using the fair value option due to the inherent nature of the liabilities and the changes in value of the underlying shares that will ultimately be issued to settle the liabilities. The estimated fair value of these liabilities is classified as Level 3 and determined based upon the number of shares that are issuable to the sellers and the quoted closing price of our common stock as of the reporting date. The number of shares that will ultimately be issued is subject to adjustment for indemnified claims that existed as of the closing date for each acquisition. Changes in the number of shares issued and share price can significantly affect the estimated fair value of the liabilities. During the year ended December 31, 2020, the change in fair value related to stock payable liabilities recorded to other income (expense), net was expense of \$37.5 million.

8. Commitments and contingencies

Leases

In 2015, we entered into an operating lease agreement for our headquarters and main production facility in San Francisco, California which commenced in 2016. This lease expires in 2026 and we may renew the lease for an additional ten years. This optional period was not considered reasonably certain to be exercised and therefore we determined the lease term to be a ten-year period expiring in 2026. In connection with the execution of the lease, we provided a security deposit of approximately \$4.6 million which is included in restricted cash in our consolidated balance sheets. We also have other operating leases for office and laboratory space in California, Colorado, Massachusetts, New York and Washington and internationally in Australia and Israel. We expect to enter into new leases and modify existing leases as we support continued growth of our operations.

We have entered into various finance lease agreements to obtain laboratory equipment. The terms of our finance leases are generally three years and are typically secured by the underlying equipment. The portion of the future payments designated as principal repayment and related interest was classified as a finance lease obligation on our consolidated balance sheets.

Supplemental information regarding our operating and finance leases were as follows:

	Year Ended December 31,	
	2020	2019
Weighted-average remaining lease term:		
Operating leases	5.4 years	6.5 years
Finance leases	2.6 years	2.0 years
Weighted-average discount rate:		
Operating leases	10.6 %	11.8 %
Finance leases	4.8 %	5.5 %
Cash payments included in the measurement of lease liabilities (in millions):		
Operating leases	\$ 11.6	\$ 10.2
Finance leases	\$ 2.0	\$ 2.1

The components of lease costs, which were included in cost of revenue, research and development, selling and marketing and general and administrative expenses on our consolidated statements of operations, were as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Operating lease costs	\$ 11,329	\$ 10,329	\$ 9,648
Sublease income	—	(173)	(156)
Finance lease costs	2,084	1,546	1,820
Total lease costs	\$ 13,413	\$ 11,702	\$ 11,312

Future payments under operating and finance leases as of December 31, 2020 are as follows (in thousands):

	Operating leases	Finance leases
2021	\$ 14,338	\$ 2,006
2022	13,788	1,908
2023	13,229	1,199
2024	13,407	26
2025	11,672	—
Thereafter	9,499	—
Future non-cancelable minimum lease payments	75,933	5,139
Less: interest	(18,787)	(321)
Total lease liabilities	57,146	4,818
Less: current portion	(8,789)	(1,695)
Lease obligations, net of current portion	\$ 48,357	\$ 3,123

Debt financing

In November 2018, we entered into a Note Purchase Agreement (the "2018 Note Purchase Agreement") pursuant to which we were eligible to borrow an aggregate principal amount up to \$200.0 million over a seven year maturity term which included an initial borrowing of \$75.0 million in November 2018. We received net proceeds of \$10.3 million after terminating and repaying the balance of our obligations of approximately \$64.7 million with our previous lender.

In September 2019, we settled our obligations under the 2018 Note Purchase Agreement in full for \$85.7 million, which included repayment of principal of \$75.0 million, accrued interest of \$2.4 million, and prepayment fees of \$8.9 million which were recorded as debt extinguishment costs in other expense, net in our consolidated statement of operations during the year ended December 31, 2019.

In October 2020, we entered into a credit agreement with a financial institution under which we borrowed \$135.0 million (the "2020 Term Loan") concurrent with the closing of the ArcherDX transaction (the "closing date"). The 2020 Term Loan is secured by a first priority lien on all of our and our subsidiaries' assets (including our intellectual property), and is guaranteed by our subsidiaries, in each case, excluding certain excluded assets and immaterial foreign subsidiaries. The 2020 Term Loan bears interest at an annual rate equal to LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75%. The 2020 Term Loan will mature on (i) June 1, 2024 if at such time our Convertible Senior Notes are outstanding and are due to mature on September 1, 2024 (provided that if, prior to such date, the maturity date of at least 80% of the Convertible Senior Notes is extended to a date that is prior to September 1, 2025 the maturity date for the 2020 Term Loan will be automatically extended to a date that is 90 days prior to such Convertible Senior Notes maturity date as extended), or (ii) otherwise, on June 1, 2025. The full amount of the 2020 Term Loan is due upon maturity. If the 2020 Term Loan is prepaid (whether such prepayment is optional or mandatory), we must pay a prepayment fee of 6% if the prepayment occurs prior to the third anniversary of the closing date or 4% if the prepayment occurs after the third anniversary of the closing date and we must also pay a make-whole fee if the prepayment occurs prior to the second anniversary of the closing date. In connection with the 2020 Term Loan, we issued warrants to purchase 1.0 million shares of our common stock with an exercise price of \$16.85 per share, exercisable through October 2027. The warrants, which were classified as equity, were recorded at an amount based on the allocated proceeds and do not require subsequent remeasurement. In October 2020, these warrants were exercised in full through net settlement resulting in the issuance of 0.7 million shares.

The credit agreement contains customary events of default and covenants, including among others, covenants limiting our ability to incur debt, incur liens, undergo a change in control, merge with or acquire other entities, make investments, pay dividends or other distributions to holders of our equity securities, repurchase stock, and dispose of assets, in each case subject to certain customary exceptions. In addition, the credit agreement contains financial covenants that require us to maintain a minimum cash balance and minimum quarterly revenue levels.

Debt discounts, including debt issuance costs, related to the 2020 Term Loan of \$32.8 million were recorded as a direct deduction from the debt liability and are being amortized to interest expense over the term of the 2020 Term Loan. Interest expense related to our debt financings, excluding the impact of our Convertible Senior Notes, was \$7.4 million, \$5.7 million and \$6.7 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Convertible Senior Notes

In September 2019, we issued, at par value, \$350.0 million aggregate principal amount of 2.00% Convertible Senior Notes due 2024 in a private offering. The Convertible Senior Notes are our senior unsecured obligations and will mature on September 1, 2024, unless earlier converted, redeemed or repurchased. The Convertible Senior Notes bear cash interest at a rate of 2.0% per year, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on March 1, 2020.

Upon conversion, the Convertible Senior Notes will be convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. Our current intent is to settle the principal amount of the Convertible Senior Notes in cash upon conversion, with any remaining conversion value being delivered in shares of our common stock. The initial conversion rate for the Convertible Senior Notes is 33.6293 shares of our common stock per \$1,000 principal amount of the Convertible Senior Notes (equivalent to an initial conversion price of approximately \$29.74 per share of common stock).

If we undergo a fundamental change (as defined in the indenture governing the Convertible Senior Notes), the holders of the Convertible Senior Notes may require us to repurchase all or any portion of their Convertible Senior Notes for cash at a repurchase price equal to 100% of the principal amount of the Convertible Senior Notes to be repurchased plus accrued and unpaid interest to, but excluding, the redemption date.

The Convertible Senior Notes will be convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding March 1, 2024, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on December 31, 2019 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the Convertible Senior Notes on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the “measurement period”) in which the trading price per \$1,000 principal amount of Convertible Senior Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (3) if we call any or all of the Convertible Senior Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or (4) upon the occurrence of specified corporate events. On or after March 1, 2024 until the close of business on the business day immediately preceding the maturity date, holders may convert their Convertible Senior Notes at any time, regardless of the foregoing circumstances. As of December 31, 2020, none of the above circumstances had occurred and therefore the Convertible Senior Notes could not have been converted. However, these notes were convertible at the option of the holders during the quarter beginning on January 1, 2021 due to the sale price of our common stock during the quarter ended December 31, 2020.

We may not redeem the Convertible Senior Notes prior to September 6, 2022. We may redeem for cash all or any portion of the Convertible Senior Notes, at our option, on or after September 6, 2022 and on or before the 30th scheduled trading day immediately before the maturity date if the last reported sale price of the Common Stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

The Convertible Senior Notes consisted of the following (in thousands):

	December 31,	
	2020	2019
Outstanding principal	\$ 350,000	\$ 350,000
Unamortized debt discount and issuance costs	(66,276)	(81,245)
Net carrying amount, liability component	<u>\$ 283,724</u>	<u>\$ 268,755</u>

As of December 31, 2020, the fair value of the Convertible Senior Notes was \$586.0 million. The estimated fair value of the Convertible Senior Notes, which are classified as Level 2 financial instruments, was determined based on the estimated or actual bid prices of the Convertible Senior Notes in an over-the-counter market. We recognized \$22.0 million and \$6.5 million of interest expense related to the Convertible Senior Notes during the years ended December 31, 2020 and 2019, respectively.

Guarantees and indemnifications

As permitted under Delaware law and in accordance with our bylaws, we indemnify our directors and officers for certain events or occurrences while the officer or director is or was serving in such capacity. The maximum amount of potential future indemnification is unlimited; however, we maintain director and officer liability insurance. This insurance allows the transfer of the risk associated with our exposure and may enable us to recover a portion of any future amounts paid. We believe the fair value of these indemnification agreements is minimal. Accordingly, we did not record any liabilities associated with these indemnification agreements at December 31, 2020 or 2019.

Other commitments

In the normal course of business, we enter into various purchase commitments primarily related to service agreements and laboratory supplies. At December 31, 2020, our total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were as follows (in thousands):

	Amount
2021	23,064
2022	20,372
2023	19,451
2024	9,220
2025	4,530
Thereafter	25,501
Total	<u>\$ 102,138</u>

In December 2020, we entered into a lease agreement in San Francisco, California for additional office and lab space. We determined the lease commencement date to be in January 2021 when we took possession of the leased premises. Total lease payments over the course of this lease will be \$45.0 million and are included in the purchase commitments above.

Contingencies

We were not a party to any material legal proceedings at December 31, 2020, or at the date of this report except for matters listed below which are related to ArcherDX which we acquired in October 2020. We cannot currently predict the outcome of these actions. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. If we were unable to prevail in any such proceedings, our consolidated financial position, results of operations, and future cash flows may be materially impacted. In addition, we are and may from time to time become involved in various legal proceedings and claims arising in the ordinary course of business. While we believe any such claims are unsubstantiated, and we believe we are in compliance with applicable laws and regulations applicable to our business, the resolution of any such claims could be material.

Natera, Inc.

On January 27, 2020, Natera filed a lawsuit against ArcherDX (a subsidiary of Invitae effective October 2, 2020) in the United States District Court for the District of Delaware, alleging that ArcherDX's products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814. On March 25, 2020, ArcherDX filed an answer denying Natera's allegations and asserting certain affirmative defenses and counterclaims, including that U.S. Patent No. 10,538,814 is invalid and not infringed. On April 15, 2020, Natera filed an answer denying ArcherDX's counterclaims and filed an amended complaint alleging that ArcherDX's products using AMP chemistry, including STRATAFIDE, PCM, LiquidPlex, ArcherMET, FusionPlex, and VariantPlex, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, U.S. Patent No. 10,590,482, and U.S. Patent No. 10,597,708, each of which are held by Natera. Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of such patents. On May 13, 2020, ArcherDX filed an answer to Natera's amended complaint denying Natera's allegations and asserting certain affirmative defenses and counterclaims, including that the asserted patents are invalid and not infringed. On June 3, 2020, Natera filed an answer denying ArcherDX's counterclaims. On June 4, 2020, ArcherDX filed a motion seeking dismissal of Natera's infringement claims against STRATAFIDE, PCM, and ArcherMET, and for a judgment that U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On August 6, 2020, Natera filed another complaint against ArcherDX in the United States District Court for the District of Delaware alleging that ArcherDX's products using AMP chemistry, including STRATAFIDE, PCM, LiquidPlex, ArcherMET, and VariantPlex, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,731,220. Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of the patent. On October 13, 2020, the court issued an order denying ArcherDX's motion for dismissal of Natera's infringement claims against STRATAFIDE, PCM, and ArcherMET, and declined to enter judgment that U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On January 12, 2021, the court issued an order granting Natera leave to amend its complaint to add Invitae as a co-defendant and plead allegations that ArcherDX and Invitae induce end-users to infringe the patents-in-suit. Natera filed its Second Amended Complaint on the same day, with service completed on January 15, 2021. ArcherDX and Invitae filed answers to the Second Amended Complaint on January 26, 2021 and February 5, 2021, respectively, denying Natera's allegations and restating certain affirmative defenses and counterclaims of non-infringement and invalidity. The litigations have now been consolidated for all purposes, are ongoing, and trial has been scheduled for May 2022.

QIAGEN Sciences

On July 10, 2018, ArcherDX and the General Hospital Corporation d/b/a Massachusetts General Hospital, which we refer to as MGH, filed a lawsuit in the United States District Court for the District of Delaware against QIAGEN Sciences, LLC, QIAGEN LLC, QIAGEN Beverly, Inc., QIAGEN Gaithersburg, Inc., QIAGEN GmbH and QIAGEN N.V., which is collectively referred to herein as QIAGEN, and a named QIAGEN executive who was a former member of ArcherDX's board of directors, alleging several causes of action, including infringement of the '810 Patent, trade secret misappropriation, breach of fiduciary duty, false advertising, tortious interference and deceptive trade practices. The '810 Patent relates to methods for preparing a nucleic acid for sequencing and aspects of ArcherDX's AMP technology. On October 30, 2019, with the permission of the Court, ArcherDX amended ArcherDX's complaint to add a claim for infringement of the '597 Patent. The '597 Patent relates to methods of preparing and analyzing nucleic acids, such as by enriching target sequences prior to sequencing, and aspects of ArcherDX's AMP technology. The QIAGEN products that ArcherDX alleges infringe the '810 Patent and the '597 Patent include, but are not limited to, QIAseq Targeted DNA Panels, QIAseq Targeted RNAscan Panels, QIAseq Index Kits and QIAseq Immune Repertoire RNA Library Kits. ArcherDX is seeking, among other things, damages for ArcherDX's lost profits due to QIAGEN's infringement and a permanent injunction enjoining QIAGEN from marketing and selling the infringing products and from using ArcherDX's trade secrets. On December 5, 2019, QIAGEN and the named QIAGEN executive submitted their answer denying the allegations in ArcherDX's complaint and asserting affirmative defenses that, among other things, the '810 Patent and '597 Patent are not infringed by QIAGEN's products, that both patents are invalid, and that the complaint fails to state any claim for which relief may be granted. This litigation is ongoing, and trial is currently scheduled for August 2021.

9. Stockholders' equity

Shares outstanding

Shares of convertible preferred and common stock were as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Convertible preferred stock:			
Shares outstanding, beginning of period	125	3,459	3,459
Conversion into common stock	—	(3,334)	—
Shares outstanding, end of period	<u>125</u>	<u>125</u>	<u>3,459</u>
Common stock:			
Shares outstanding, beginning of period	98,796	75,481	53,597
Common stock issued in private placement	16,320	—	374
Common stock issued in connection with public offering	24,005	11,136	17,103
Common stock issued on exercise of stock options, net	2,659	468	351
Common stock issued pursuant to vesting of RSUs	5,304	2,683	1,369
Common stock issued pursuant to exercises of warrants	968	31	1,099
Common stock issued pursuant to employee stock purchase plan	671	455	566
Common stock issued pursuant to acquisitions	37,163	5,208	1,022
Common stock issued upon conversion of preferred stock	—	3,334	—
Shares outstanding, end of period	<u>185,886</u>	<u>98,796</u>	<u>75,481</u>

2018 Sales Agreement

In August 2018, we entered into a Common Stock Sales Agreement (the "2018 Sales Agreement") with Cowen and Company, LLC ("Cowen"), under which we could offer and sell from time to time at our sole discretion shares of our common stock through Cowen as our sales agent, in an aggregate amount not to exceed \$75.0 million. Cowen may sell the shares by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933, including without limitation sales made directly on The New York Stock Exchange, and also may sell the shares in privately negotiated transactions, subject to our prior approval. Per the terms of the agreement, Cowen receives a commission equal to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2018 Sales Agreement. In March 2019, we amended the 2018 Sales Agreement to increase the aggregate amount of our common stock to be sold under this agreement to an amount not to exceed \$175.0 million.

During the year ended December 31, 2020, we sold a total of 3.6 million shares of common stock under the 2018 Sales Agreement at an average price of \$26.33 per share, for gross proceeds of \$93.7 million and net proceeds of \$90.7 million.

During the year ended December 31, 2019, we sold a total of 0.8 million shares of common stock under the 2018 Sales Agreement at an average price of \$25.71 per share, for gross proceeds of \$20.2 million and net proceeds of \$19.5 million.

During the year ended December 31, 2018, we sold a total of 4.3 million shares of common stock under the 2018 Sales Agreement at an average price of \$14.13 per share, for aggregate gross proceeds of \$61.1 million and net proceeds of \$58.9 million.

Public offerings

In January 2021, we issued, in an underwritten public offering, an aggregate of 8.9 million shares of our common stock at a price of \$51.50 per share, for gross proceeds of \$460.0 million and net proceeds of approximately \$434.3 million.

In April 2020, we issued, in an underwritten public offering, an aggregate of 20.4 million shares of our common stock at a price of \$9.00 per share, for gross proceeds of \$184.0 million and net proceeds of \$173.0 million.

In March 2019, we sold, in an underwritten public offering, an aggregate of 10.4 million shares of our common stock at a price of \$19.00 per share, for gross proceeds of \$196.7 million and net proceeds of \$184.5 million.

Private placement

In August 2017, in a private placement to certain accredited investors, we issued 5.2 million shares of common stock at a price of \$8.50 per share, and 3.5 million shares of our Series A convertible preferred stock at a price of \$8.50 per share, for gross proceeds of approximately \$73.5 million and net proceeds of \$68.9 million. The Series A preferred stock is convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like. During the year ended December 31, 2019, 3.3 million shares of Series A convertible preferred stock were converted to 3.3 million shares of common stock.

In connection with our acquisition of ArcherDX, in June 2020 we entered into a definitive agreement to sell \$275.0 million in common stock in a private placement at a price of \$16.85 per share. The private placement closed in October 2020, concurrently with our acquisition of ArcherDX. We received proceeds of \$5.0 million from the private placement during September 2020 and the remainder of the proceeds were received in October 2020.

Common stock warrants

As of December 31, 2020, we had outstanding warrants to purchase common stock as follows:

Warrant	Issuance Date	Expiration Date	Exercise Price Per Share	Number of Shares of Common Stock Underlying Warrants
Warrants issued in exchange for CombiMatrix Series F warrants	November 2017	March 2021	\$ 5.95	214,154

The exercise price of warrants issued in exchange for CombiMatrix Series F warrants was determined pursuant to the terms of the acquisition.

10. Stock incentive plans

Stock incentive plans

In 2010, we adopted the 2010 Incentive Plan (the “2010 Plan”). The 2010 Plan provides for the granting of stock-based awards to employees, directors and consultants under terms and provisions established by our Board of Directors. Under the terms of the 2010 Plan, options may be granted at an exercise price not less than the fair market value of our common stock. For employees holding more than 10% of the voting rights of all classes of stock, the exercise prices for incentive and nonstatutory stock options must be at least 110% of fair market of our common stock on the grant date, as determined by our Board of Directors. The terms of options granted under the 2010 Plan may not exceed ten years.

In January 2015, we adopted the 2015 Stock Incentive Plan (the “2015 Plan”), which became effective upon the closing of our initial public offering (“IPO”). Shares outstanding under the 2010 Plan were transferred to the 2015 Plan upon effectiveness of the 2015 Plan. The 2015 Plan provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 through January 1, 2025. In addition, shares subject to awards under the 2010 Plan that are forfeited or terminated will be added to the 2015 Plan. The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock units, stock appreciation rights and other forms of equity compensation, all of which may be granted to employees, including officers, non-employee directors and consultants. Additionally, the 2015 Plan provides for the grant of cash-based awards.

Options granted generally vest over a period of four years. Typically, the vesting schedule for options granted to newly hired employees provides that 1/4 of the award vests upon the first anniversary of the employee’s date of hire, with the remainder of the award vesting monthly thereafter at a rate of 1/48 of the total shares subject to the option. All other options typically vest in equal monthly installments over the four-year vesting schedule. Upon the acquisition of ArcherDX, any option that was outstanding was converted into a fully vested option to purchase a share of our common stock which resulted in the issuance of 3.7 million options.

RSUs generally vest over a period of three years. Typically, the vesting schedule for RSUs provides that 1/3 of the award vests upon each anniversary of the grant date, with certain awards that include a portion that vests immediately upon grant. In June 2019, we granted Time-based RSUs in connection with the acquisition of Singular Bio which vest in three equal installments over a period of 18 months and PRSUs that vest based on the achievement of performance conditions. In December 2020, we granted RSUs in connection with an asset acquisition which vest in two equal installments in December 2021 and December 2022, subject to the employee’s continued service with us.

Under our management incentive compensation plan, in July 2019 we granted PRSUs to our executive officers as well as other specified senior level employees based on the level of achievement of a specified 2019 revenue goal. One-third of the 0.8 million shares that were ultimately awarded under this plan vested during the year ended December 31, 2020 and the remaining shares will vest through March 2022. In June 2020, we granted 0.3 million PRSUs under this plan which are based on the level of achievement of a specified 2020 cash burn goal. Upon achievement of the specified 2020 cash burn goal, 0.3 million shares were ultimately awarded and began vesting in 2021 over a one year period. These PRSUs had a grant date fair value of \$4.2 million based on an estimated issuance of 0.3 million shares and expectation of the performance conditions. During the year ended December 31, 2020, \$2.1 million was recorded as stock-based compensation expense related to the awards. No PRSUs were granted during the year ended December 31, 2018.

Activity under the 2010 Plan and the 2015 Plan is set forth below (in thousands, except per share amounts and years):

	Shares Available For Grant	Stock Options Outstanding	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Balance at December 31, 2019	5,444	3,542	\$ 9.49	6.1	\$ 24,966
Additional shares reserved	9,019	—			
Options granted	(4,005)	4,005	\$ 3.74		
Options cancelled	11	(11)	\$ 7.05		
Options exercised	—	(2,659)	\$ 4.04		
RSUs and PRSUs granted ⁽¹⁾	(3,502)	—			
RSUs and PRSUs cancelled	480	—			
Balance at December 31, 2020	<u>7,447</u>	<u>4,877</u>	\$ 7.75	6.8	\$ 166,130
Options exercisable at December 31, 2020		<u>4,432</u>	\$ 6.86	6.6	\$ 154,907
Options vested and expected to vest at December 31, 2020		<u>4,809</u>	\$ 7.62	6.7	\$ 164,410

⁽¹⁾ Includes the changes in time-based RSUs and PRSUs granted as a part of the Singular Bio acquisition in June 2019 and shares granted in an asset acquisition in December 2020 which are based on a fixed dollar value. The number of shares issued will be variable until the awards vest.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of our common stock for stock options that were in-the-money.

The weighted-average fair value of options to purchase common stock granted was \$10.10, \$14.52 and \$4.87 in the years ended December 31, 2020, 2019 and 2018, respectively.

The total grant-date fair value of options to purchase common stock vested was \$2.8 million, \$4.3 million and \$5.9 million in the year ended December 31, 2020, 2019, and 2018, respectively.

The intrinsic value of options to purchase common stock exercised was \$104.4 million, \$6.3 million and \$1.7 million in the years ended December 31, 2020, 2019 and 2018, respectively.

The following table summarizes RSU, including PRSU, activity (in thousands, except per share data):

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance at December 31, 2019	8,885	\$ 15.17
RSUs granted	4,874	\$ 20.35
Time-based RSUs and PRSUs granted - variable ⁽¹⁾	(1,646)	\$ 24.12
PRSUs granted	274	\$ 16.17
RSUs vested	(5,305)	\$ 19.76
RSUs cancelled	(480)	\$ 18.23
Balance at December 31, 2020	<u>6,602</u>	<u>\$ 12.89</u>

⁽¹⁾ Includes the changes in the Time-based RSUs and PRSUs granted as a part of the Singular Bio acquisition in June 2019 and the shares granted in an asset acquisition in December 2020 which are based on a fixed dollar value. The number of shares issued will be variable until the awards vest. The weighted-average grant date fair value per share reflects the fair value pricing of the full award.

2015 Employee Stock Purchase Plan

In January 2015, we adopted the 2015 Employee Stock Purchase Plan (the “ESPP”), which became effective upon the closing of the IPO. Employees participating in the ESPP may purchase common stock at 85% of the lesser of the fair market value of common stock on the purchase date or last trading day preceding the offering date. At December 31, 2020, cash received from payroll deductions pursuant to the ESPP was \$1.8 million.

The ESPP provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 and continuing through January 1, 2025. At December 31, 2020, a total of 0.9 million shares of common stock are reserved for issuance under the ESPP.

Stock-based compensation

We use the grant date fair value of our common stock to value options when granted. In determining the fair value of stock options and ESPP purchases, we use the Black-Scholes option-pricing model and, for stock options, the assumptions discussed below. Each of these inputs is subjective and its determination generally requires significant judgment. The fair value of RSU and PRSU awards is based on the grant date share price. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and RSUs and on an accelerated basis for PRSUs.

Expected term—The expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method (based on the midpoint between the vesting date and the end of the contractual term).

Expected volatility—We estimate expected volatility based on the historical volatility of our common stock over a period equal to the expected term of stock option grants and RSUs and over the expected six-month term ESPP purchase periods.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Dividend yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

The fair value of share-based payments for stock options granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model based on the following assumptions:

	Year Ended December 31,		
	2020	2019	2018
Expected term (in years)	6.0	6.0	6.0
Expected volatility	71.0%	64.2%	59.6%
Risk-free interest rate	0.5%	2.6%	2.8%

The fair value of shares purchased pursuant to the ESPP is estimated using the Black-Scholes option pricing model. For the years ended December 31, 2020, 2019 and 2018, the weighted-average grant date fair value per share for the ESPP was \$10.98, \$6.05 and \$3.26, respectively.

The fair value of the shares purchased pursuant to the ESPP was estimated using the following assumptions:

	Year Ended December 31,		
	2020	2019	2018
Expected term (in years)	0.5	0.5	0.5
Expected volatility	105.7%	66.3%	71.7%
Risk-free interest rate	0.1%	2.0%	2.1%

The following table summarizes stock-based compensation expense for the years ended December 31, 2020, 2019 and 2018, included in the consolidated statements of operations (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Cost of revenue	\$ 8,713	\$ 4,563	\$ 2,960
Research and development	91,762	52,450	7,017
Selling and marketing	14,418	7,641	4,887
General and administrative	43,854	11,294	5,986
Total stock-based compensation expense	\$ 158,747	\$ 75,948	\$ 20,850

At December 31, 2020, unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was \$3.1 million, which we expect to recognize on a straight-line basis over a weighted-average period of 2.4 years. Unrecognized compensation expense related to RSUs, including PRSUs, and awards that are contingently issuable upon the completion of certain milestones related to our acquisition of ArcherDX at December 31, 2020, net of estimated forfeitures, was \$144.2 million, which we expect to recognize on a straight-line basis over a weighted-average period of 1.6 years.

11. Income taxes

We recorded a benefit for income taxes in the years ended December 31, 2020, 2019 and 2018. The components of net loss before taxes by U.S. and foreign jurisdictions are as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
United States	\$ 712,409	\$ 260,531	\$ 132,194
Foreign	1,861	(116)	(39)
Total	\$ 714,270	\$ 260,415	\$ 132,155

The components of the provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Current:			
Foreign	171	85	62
Total current benefit for income taxes	171	85	62
Deferred:			
Federal	(94,279)	(16,011)	(2,862)
State	(17,730)	(2,524)	—
Foreign	(262)	—	—
Total deferred benefit for income taxes	(112,271)	(18,535)	(2,862)
Total income tax benefit	\$ (112,100)	\$ (18,450)	\$ (2,800)

The following table presents a reconciliation of the tax expense computed at the statutory federal rate and our tax expense for the periods presented:

	Year Ended December 31,		
	2020	2019	2018
U.S. federal taxes at statutory rate	21.0 %	21.0 %	21.0 %
State taxes (net of federal benefit)	3.4 %	3.7 %	5.2 %
Stock-based compensation	(1.6)%	1.3 %	(0.7)%
Research and development credits	1.1 %	— %	2.7 %
Non-deductible expenses	(1.5)%	(1.6)%	(0.6)%
Change in valuation allowance	(6.7)%	(17.3)%	(25.5)%
Total	15.7 %	7.1 %	2.1 %

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	As of December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	\$ 337,866	\$ 173,182
Tax credits	19,969	—
Revenue recognition differences	9,099	5,138
Leasing Liabilities	14,274	11,626
Accruals and other	37,677	14,391
Gross deferred tax assets	418,885	204,337
Valuation allowance	(209,308)	(145,318)
Total deferred tax assets	209,577	59,019
Deferred tax liabilities:		
Amortization and depreciation	(233,150)	(30,875)
Convertible Senior Notes	(14,658)	(17,720)
Leasing Assets	(13,307)	(10,424)
Total deferred tax liabilities	(261,115)	(59,019)
Net deferred tax liabilities	\$ (51,538)	\$ —

In December 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law making significant changes to the Internal Revenue Code. Changes included among other items, a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%. Although the Tax Act was generally effective January 1, 2018, GAAP required recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017. As a result of the lower corporate tax rate enacted as part of the Tax Act, during 2017, the Company recorded a provisional estimate to reduce deferred tax assets by \$48.8 million offset by a corresponding reduction in the valuation allowance resulting in no net impact to our income tax benefit or expense.

In December 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, during 2017, we recorded a provisional estimate which resulted in a \$48.8 million reduction in deferred tax assets and in the fourth quarter of 2018, we completed our analysis of the impact of the Tax Act and determined that no material adjustments were required to the provisional amounts previously recorded.

We historically established a full valuation allowance against our deferred tax assets due to the uncertainty surrounding realization of such assets. In 2020, we released approximately \$112.1 million of our valuation allowance to account for acquired intangibles that support the future realization of some of our deferred tax assets. Due to the overall increase of deferred tax assets, our valuation allowance also increased from the prior year. Our valuation allowance increased by \$64.0 million, \$23.4 million, and \$26.3 million during the years ended December 31, 2020, 2019, and 2018, respectively.

As of December 31, 2020, we had net operating loss carryforwards of approximately \$1.4 billion and \$890.6 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. Of the \$1.4 billion, \$284.9 million will begin to expire in 2030 while \$1.1 billion have no expiration date. The state net operating loss carryforwards will begin to expire in 2030.

As of December 31, 2020, we had research and development credit carryforwards of approximately \$26.2 million and \$17.6 million available to reduce our future tax liability, if any, for federal and state income tax purposes, respectively. The federal credit carryforwards begin to expire in 2030. California credit carryforwards have no expiration date.

Internal Revenue Code ("IRC") section 382 places a limitation (the "Section 382 limitation" or "annual limitation") on the amount of taxable income that can be offset by net operating loss carryforwards after a change in control (generally greater than 50% change in ownership) of a loss corporation. Similar provisions exist for states. In addition, and as a result of the acquisitions of Good Start Genetics and CombiMatrix in 2017, acquisitions of Singular Bio, Jungla, and Clear Genetics in 2019, and acquisitions of YouScript and ArcherDX in 2020, tax loss carryforwards from acquired entities are also subject to the Section 382 limitation due to the change in control in the acquired entities in the current year.

In addition, as a result of equity issued in connection with various acquisitions, we also performed a section 382 analysis in 2020 with respect to our operating loss and credit carryforwards. We concluded while an ownership change occurred in 2019 as defined under IRC section 382, none of our net operating loss carryforwards would expire unused solely as a result of annual limitations imposed on the use of the carryforwards under IRC sections 382 and 383.

As of December 31, 2020, we had unrecognized tax benefits of \$22.0 million, which primarily relates to research and development credits, none of which would currently affect our effective tax rate if recognized due to our valuation allowance against our deferred tax assets. During the year, we benchmarked the reserves of similar tax positions within the industry based on IRS and state audits of comparable companies. Based on our analysis, we decreased our unrecognized tax benefits to more closely align with other comparable companies within the industry. As these reserves relate primarily to research and development credits which have a full valuation allowance, such adjustments did not impact our income tax provision. Unrecognized tax benefits are not expected to materially change in the next 12 months.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year ended December 31,		
	2020	2019	2018
Unrecognized tax benefits, beginning of period	\$ 26,985	\$ 16,375	\$ 10,561
Gross increases—current period tax positions	8,368	10,311	5,686
Gross increases—prior period tax positions	53	299	128
Gross decreases—prior period tax positions	(13,441)	—	—
Unrecognized tax benefits, end of period	\$ 21,965	\$ 26,985	\$ 16,375

Our policy is to include penalties and interest expense related to income taxes as a component of tax expense. We have not accrued interest and penalties related to the unrecognized tax benefits reflected in the financial statements for the years ended December 31, 2020, 2019 and 2018.

Our major tax jurisdictions are the United States and California. All of our tax years will remain open for examination by the Federal and state tax authorities for three and four years, respectively, from the date of utilization of the net operating loss or research and development credit. We do not have any tax audits pending.

12. Net loss per share

The following table presents the calculation of basic and diluted net loss per share (in thousands, except per share data):

	Year ended December 31,		
	2020	2019	2018
Net loss	\$ (602,170)	\$ (241,965)	\$ (129,355)
Shares used in computing net loss per share, basic and diluted	134,587	90,859	66,747
Net loss per share, basic and diluted	\$ (4.47)	\$ (2.66)	\$ (1.94)

The following common stock equivalents have been excluded from diluted net loss per share because their inclusion would be anti-dilutive (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Shares of common stock subject to outstanding options	6,878	3,662	4,028
Shares of common stock subject to outstanding warrants	405	592	1,513
Shares of common stock subject to outstanding RSUs	5,590	5,293	3,476
Shares of common stock subject to outstanding PRSUs	1,658	1,860	—
Shares of common stock pursuant to ESPP	294	239	294
Shares of common stock underlying Series A convertible preferred stock	125	702	3,459
Shares of common stock subject to Convertible Senior Notes conversion	8,371	3,612	—
Total shares of common stock equivalents	23,321	15,960	12,770

13. Geographic information

Revenue by country is determined based on the billing address of the customer and is summarized as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
United States	\$ 255,680	\$ 202,550	\$ 138,239
Canada	4,529	4,356	4,206
Rest of world	19,389	9,918	5,254
Total revenue	\$ 279,598	\$ 216,824	\$ 147,699

As of December 31, 2020, 2019 and 2018, our long-lived assets were primarily located in the United States other than operating lease assets representing our right-of-use for leased facilities in Israel and Australia.

14. Selected quarterly data (unaudited)

The following table summarizes our quarterly financial information for 2020 and 2019 (in thousands, except per share amounts):

	Three Months Ended			
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
Revenue	\$ 64,248	\$ 46,191	\$ 68,728	\$ 100,431
Cost of revenue	\$ 40,422	\$ 42,952	\$ 46,643	\$ 68,258
Loss from operations	\$ (97,784)	\$ (142,082)	\$ (80,823)	\$ (331,483)
Net loss	\$ (98,527)	\$ (166,403)	\$ (102,902)	\$ (234,338)
Net loss per share, basic and diluted ⁽¹⁾	\$ (0.99)	\$ (1.29)	\$ (0.78)	\$ (1.30)

	Three Months Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Revenue	\$ 40,553	\$ 53,475	\$ 56,511	\$ 66,285
Cost of revenue	\$ 21,254	\$ 28,006	\$ 32,120	\$ 36,723
Loss from operations	\$ (36,207)	\$ (51,886)	\$ (76,983)	\$ (79,036)
Net loss	\$ (37,677)	\$ (48,676)	\$ (78,707)	\$ (76,905)
Net loss per share, basic and diluted ⁽¹⁾	\$ (0.47)	\$ (0.54)	\$ (0.82)	\$ (0.79)

⁽¹⁾ Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of quarterly net loss per share information may not equal annual net loss per share.

15. Subsequent event

In February 2021, we acquired 100% of the equity interest of Reference Genomics, Inc. d/b/a One Codex "One Codex", a company developing and commercializing products and services relating to microbiome sequencing, analysis and reporting, for upfront consideration consisting of 1.2 million shares of our common stock and \$17.0 million in cash. Up to approximately \$0.1 million in cash and 0.2 million additional shares of our common stock are subject to a hold back to satisfy indemnification obligations that may arise following the closing. Given the timing of the closing of the transaction with One Codex, we are currently in the process of valuing the assets acquired and liabilities assumed. As a result, we are not yet able to provide the amounts to be recognized as of the acquisition date for the major classes of assets acquired and liabilities assumed and other related disclosures. We will disclose this and other related information in our Quarterly Report on Form 10-Q for the three months ending March 31, 2021.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

ITEM 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer) have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation described in Item 9A above that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining internal control over our financial reporting. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

The scope of management's assessment of the effectiveness of our internal control over financial reporting excludes the operations of ArcherDX, which we acquired in October 2020. This exclusion is in accordance with the SEC's general guidance that an assessment of a recently acquired business may be omitted from the scope of our evaluation in the year of acquisition. ArcherDX constituted 3% of our consolidated total assets and 6% of our consolidated revenue as of and for the year ended December 31, 2020.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework (2013 Framework). Based on the assessment using those criteria, our management concluded that, as of December 31, 2020, our internal control over financial reporting was effective. Our independent registered public accounting firm, Ernst & Young LLP, has issued an audit report with respect to our internal control over financial reporting, which appears in Part II, Item 8 of this Annual Report on Form 10-K.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Invitae Corporation

Opinion on Internal Control Over Financial Reporting

We have audited Invitae Corporation's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Invitae Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

As indicated in the accompanying Management's Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of ArcherDX, Inc., which is included in the 2020 consolidated financial statements of the Company and constituted 3% and 1% of total and net assets, respectively, as of December 31, 2020 and 6% and 4% of revenues and net loss, respectively, for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of ArcherDX, Inc.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Invitae Corporation as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements") and our report dated February 26, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Redwood City, California

February 26, 2021

ITEM 9B. Other Information.

None.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance.

The information required by this item with respect to directors is incorporated by reference from the information under the caption "Election of Directors," contained in our proxy statement to be filed with the Securities and Exchange Commission no later than 120 days from the end of our fiscal year ended December 31, 2020 in connection with the solicitation of proxies for our 2021 Annual Meeting of Stockholders, or the Proxy Statement. Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption "Information About our Executive Officers" and is incorporated herein by reference.

There have been no material changes to the procedures by which stockholders may recommend nominees to our Board of Directors.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. To the extent disclosure for delinquent reports is being made, it can be found under the caption "Delinquent Section 16(a) Reports" in the Proxy Statement and is incorporated herein by reference.

Our board of directors has adopted a code of business conduct and a code of ethics for senior financial officers applicable to our Chief Executive Officer and Chief Financial Officer as well as other key management employees addressing ethical issues. The code of business conduct and the code of ethics are each posted on our website www.invitae.com. The code of business conduct and the code of ethics can only be amended by the approval of a majority of our board of directors. Any waiver to the code of business conduct for an executive officer or director or any waiver of the code of ethics may only be granted by our board of directors or our nominating and corporate governance committee and must be timely disclosed as required by applicable law. We have implemented whistleblower procedures that establish formal protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures will be communicated promptly to our audit committee. Stockholders may request a free copy of our code of business conduct and code of ethics by contacting Invitae Corporation, Attention: Chief Financial Officer, 1400 16th Street, San Francisco, California 94103. None of the materials on, or accessible through, our website is part of this report or incorporated by reference herein.

To date, there have been no waivers under our code of business conduct or code of ethics. We intend to disclose future amendments to certain provisions of our code of business conduct or code of ethics or waivers of such codes granted to executive officers and directors on our website at <http://www.invitae.com> within four business days following the date of such amendment or waiver.

Our Board of Directors has appointed an Audit Committee, comprised of Geoffrey S. Crouse, Christine M. Gorjanc, and Kimber D. Lockhart. The Board of Directors has determined that each of the members of our Audit Committee qualifies as an Audit Committee Financial Expert under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an "independent director" under the current rules of the New York Stock Exchange and Securities and Exchange Commission rules and regulations.

ITEM 11. Executive Compensation.

The information required by this item is incorporated by reference from the information under the captions "Election of Directors-Director Compensation" and "Executive Compensation" contained in the Proxy Statement.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to the disclosure appearing under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" contained in the Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference from the information under the captions "Certain Relationships and Related Transactions," "Corporate Governance" and "Director Independence" contained in the Proxy Statement.

ITEM 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference from the information under the caption "Ratification of the Appointment of Independent Registered Public Accounting Firm" contained in the Proxy Statement.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules.

- (a) Documents filed as part of this report
1. *Financial Statements*: Reference is made to the Index to Financial Statements of Invitae Corporation included in Item 8 of Part II hereof.
 2. *Financial Statement Schedules*: All schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto.
 3. *Exhibits*: See Item 15(b) below. Each management contract or compensating plan or arrangement required to be filed has been identified.

(b) Exhibits

Exhibit Number	Description
2.1 [@]	<u>Agreement and Plan of Merger and Plan of Reorganization, dated as of June 21, 2020, by and among Invitae Corporation, Apollo Merger Sub A Inc., Apollo Merger Sub B LLC, ArcherDX, Inc. and Kyle Lefkoff, solely in his capacity as holders' representative (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed June 24, 2020).</u>
2.2 [@]	<u>Stock Purchase and Merger Agreement, dated as of July 11, 2019, by and among Invitae Corporation, Jumanji, LLC, Jungla Inc., and Fortis Advisors LLC (incorporated by reference to Exhibit 2.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019).</u>
2.3 ^{@^}	<u>Agreement and Plan of Merger, dated as of November 8, 2019, by and among Invitae Corporation, Catalina Merger Sub A Inc., Catalina Merger Sub B LLC, Clear Genetics, Inc. and Shareholder Representative Services LLC (incorporated by reference to Exhibit 2.3 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019).</u>
2.4 ^{@^}	<u>Share Purchase Agreement, dated as of March 10, 2020, by and among Invitae Corporation, Invitae Netherlands, B.V. and Peter Schols (incorporated by reference to Exhibit 2.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020).</u>
2.5 ^{@^}	<u>Agreement and Plan of Merger, dated as of March 10, 2020, by and among Invitae Corporation, Yasawa Merger Sub A Inc., Yasawa Merger Sub B LLC, YouScript Incorporated, and Fortis Advisors LLC, as representative of YouScript Incorporated's stockholders (incorporated by reference to Exhibit 2.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020).</u>
2.6 ^{@^}	<u>Unit Purchase Agreement, dated as of March 10, 2020, by and among Invitae Corporation, David Colaizzi, Chris Howlett, Anthony Muhlenkamp, Gerald Schneider, and Matt Lehrian (incorporated by reference to Exhibit 2.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020).</u>
2.7 [@]	<u>Agreement and Plan of Merger and Plan of Reorganization, dated as of June 21, 2020, by and among Invitae Corporation, Apollo Merger Sub A Inc., Apollo Merger Sub B LLC, ArcherDX, Inc. and Kyle Lefkoff, solely in his capacity as holders' representative (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed June 24, 2020).</u>
3.1	<u>Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed February 23, 2015).</u>
3.1.1	<u>Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Invitae Corporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
3.2	<u>Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed February 23, 2015).</u>
4.1 [*]	<u>Form of Common Stock Certificate.</u>
4.2	<u>Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019).</u>
4.3	<u>Amended and Restated Registration Rights Agreement, dated as of July 31, 2017 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
4.4	<u>Form of Invitae Corporation Series F Warrant (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-4 (File No. 333-220447), as amended, filed September 13, 2017).</u>
4.5	<u>Form of Invitae Corporation Series F Warrant Agent Agreement (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-4 (File No. 333-220447), as amended, filed September 13, 2017).</u>

Exhibit Number	Description
4.6	<u>Form of Registration Rights Agreement by and among Invitae Corporation and certain stockholders of Singular Bio, Inc. (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019).</u>
4.7	<u>Form of Registration Rights Agreement by and among Invitae Corporation and certain stockholders of Jungla Inc. (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019).</u>
4.8	<u>Form of Registration Rights Agreement by and among Invitae Corporation and certain stockholders of Clear Genetics, Inc. (incorporated by reference to Exhibit 4.8 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019).</u>
4.9	<u>Indenture dated as of September 10, 2019, between Invitae Corporation and U.S. Bank National Association, as trustee (including form of Note) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed September 11, 2019).</u>
4.10	<u>Registration Rights Agreement, dated as of March 10, 2020, by and between Invitae Corporation and Peter Schols (incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report for the quarter ended March 31, 2020).</u>
4.11	<u>Registration Rights Agreement, dated as of April 1, 2020, by and among Invitae Corporation and certain stockholders of YouScript Incorporated (incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020).</u>
4.12	<u>Registration Rights Agreement, dated as of April 1, 2020, by and among Invitae Corporation, CFH Management, L.P., as assignee of David Colaizzi, Chris Howlett, Anthony Muhlenkamp, Gerald Schneider, and Matt Lehrian (incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020).</u>
4.13	<u>Registration Rights Agreement, dated as of October 2, 2020, by and among Invitae Corporation and the investors party thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed October 5, 2020).</u>
4.14*	<u>Registration Rights Agreement, dated as of December 8, 2020, by and between Invitae Corporation and IntelliGene Health Informatics, LLC.</u>
10.1#	<u>Securities Purchase Agreement, dated as of June 21, 2020, by and among Invitae Corporation and the investors identified therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 24, 2020).</u>
10.2#	<u>Registration Rights Agreement, dated as of October 2, 2020, by and among Invitae Corporation and the investors party thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed October 5, 2020).</u>
10.3#	<u>Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed October 5, 2020).</u>
10.4#	<u>Support Agreement, dated as of September 23, 2020, by and among Invitae Corporation and certain securityholders of ArcherDX, Inc. (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed October 5, 2020).</u>
10.5#	<u>Invitae Corporation 2015 Stock Incentive Plan, as amended and restated as of December 7, 2020.</u>
10.6#	<u>Form of Notice of Stock Option Grant and Non-Qualified Stock Option Agreement for awards granted under the 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S 1 (File No. 333 201433), as amended, declared effective on February 11, 2015).</u>
10.7#	<u>Form of Notice of Restricted Stock Award and Restricted Stock Agreement for awards granted under the 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S 1 (File No. 333 201433), as amended, declared effective on February 11, 2015).</u>
10.8#	<u>Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement for Awards Granted under the 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8 K filed August 6, 2015).</u>
10.9#	<u>Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S 1 (File No. 333 201433), as amended, declared effective on February 11, 2015).</u>
10.10#	<u>Form of Notice of Time-Based Restricted Stock Unit Award and Time-Based Restricted Stock Unit Agreement for Awards Granted under the Invitae Corporation 2015 Stock Incentive Plan (Inducement) (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019).</u>

Exhibit Number	Description
10.11 [#]	Form of Notice of Performance-Based Restricted Stock Unit Award and Performance-Based Restricted Stock Unit Agreement for Awards under the Invitae Corporation 2015 Stock Incentive Plan (Inducement) (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019).
10.12 [#]	Offer Letter, dated as of May 19, 2017, by and between Invitae Corporation and Shelly Guyer (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 1, 2017).
10.13	Lease Agreement dated as of September 2, 2015 by and between Invitae Corporation and 1400 16th Street LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed September 4, 2015).
10.14	Form of Warrant to Purchase Common Stock between Oxford Capital, LLC and Invitae Corporation (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016).
10.15	Sales Agreement dated as of August 9, 2018 between Invitae Corporation and Cowen and Company, LLC (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018).
10.16	Amendment No. 1 to Sales Agreement dated as of February 28, 2019 by and between Invitae Corporation and Cowen and Company, LLC (incorporated by reference to Exhibit 1.2 to the Registrant's Current Report on Form 8-K filed March 1, 2019).
10.17 [#]	Offer Letter, dated as of June 1, 2020, by and between Invitae Corporation and Kenneth D. Knight (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed June 26, 2020).
10.18	Securities Purchase Agreement, dated as of June 21, 2020, by and among Invitae Corporation and the investors identified therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 24, 2020).
10.19	Support Agreement, dated as of September 23, 2020, by and among Invitae Corporation and certain securityholders of ArcherDX, Inc. (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed October 5, 2020).
10.20 [^]	Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed October 5, 2020).
10.21 [#] *	ArcherDX, Inc. 2015 Equity Incentive Plan, as amended, and forms of agreements thereunder.
21.1*	List of Subsidiaries.
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (contained on the signature page to this Form 10-K).
31.1*	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Principal Financial and Accounting Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 ⁺	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
32.2 ⁺	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document and included as Exhibit 101).

Indicates management contract or compensatory plan or arrangement.

* Filed herewith.

@ The schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

^ Portions of this Exhibit have been redacted in accordance with Item 601 of Regulation S-K

Copies of the above exhibits not contained herein are available to any stockholder, upon payment of a reasonable per page fee, upon written request to: Chief Financial Officer, Invitae Corporation, 1400 16th Street, San Francisco, California 94103.

(c) Financial Statement Schedules: Reference is made to Item 15(a) 2 above.

ITEM 16. Form 10-K Summary.

Not applicable.

EXHIBIT 4

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

[] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File No. 001-36847



Invitae Corporation

(Exact name of the registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

27-1701898

(I.R.S. Employer Identification No.)

1400 16th Street, San Francisco, California 94103

(Address of principal executive offices, Zip Code)

(415) 374-7782

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Table with 3 columns: Title of each class, Trading Symbol, Name of exchange on which registered. Row 1: Common Stock, \$0.0001 par value per share, NVTA, New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [] No [X]

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No []

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No []

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [X] Accelerated filer [] Non-accelerated filer [] Smaller reporting company [] Emerging growth company []

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. []

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. [X]

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. []

Indicate by check mark whether any of those error corrections are restatements that required recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). []

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes [] No [X]

As of June 30, 2022, the aggregate market value of common stock held by non-affiliates of the Registrant was approximately \$569.8 million, based on the closing price of the common stock as reported on The New York Stock Exchange for that date.

The number of shares of the registrant's Common Stock outstanding as of February 24, 2023 was 246,235,501.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K incorporate by reference information from the registrant's proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant's 2023 Annual Meeting of Stockholders.

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SIGNATURES

Forward-Looking Statements

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this report other than statements of historical fact, including statements identified by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect” and similar expressions, are forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our views regarding the future of genetic testing and its role in mainstream medical practice;
- the impact of the COVID-19 pandemic on our business and the actions we have taken or may take in response thereto;
- our mission and strategy for our business, products and technology;
- the implementation of our business model and our success of our strategic realignment efforts;
- the expected costs and benefits of our strategic realignment, including anticipated annualized cash savings, and our ability to achieve positive operating cash flow;
- the expected benefits from and our ability to integrate our acquisitions;
- our ability to obtain regulatory approvals for our tests;
- the rate and degree of market acceptance of our tests and genetic testing generally;
- our ability to scale our infrastructure and operations in a cost-effective manner;
- our expectations regarding our platform and future offerings;
- the timing and results of studies with respect to our tests;
- developments and projections relating to our competitors and our industry;
- our competitive strengths;
- the degree to which individuals will share genetic information generally, as well as share any related potential economic opportunities with us;
- our commercial plans;
- our ability to obtain and maintain adequate reimbursement for our tests;
- regulatory, political and other developments in the United States and foreign countries;
- our ability to attract and retain key scientific, sales, engineering or management personnel;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- the effects of litigation or investigations on our business;
- our ability to obtain funding for our operations and to service and repay our debt;
- our future financial performance;
- our beliefs regarding our future growth and the drivers of such growth;
- our expectations regarding environmental, social and governance matters;
- the impact of accounting pronouncements and our critical accounting policies, judgments, estimates and assumptions on our financial results;
- our expectations regarding our future revenue, cost of revenue, operating expenses and capital expenditures, and our future capital requirements;
- the impact of macroeconomic conditions, including inflation and recession, on our business; and
- the impact of tax laws on our business.

Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. Although we believe that the expectations and assumptions reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Any forward-looking statements in this report speak only as of the date of this report. We expressly disclaim any obligation or undertaking to update any forward-looking statements.

In this report, all references to “Invitae,” “we,” “us,” “our,” or “the Company” mean Invitae Corporation.

Invitae and the Invitae logo are trademarks of Invitae Corporation. We also refer to trademarks of other companies and organizations in this report.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties that could affect our ability to successfully implement our business strategy and affect our financial results. You should carefully consider all of the information in this Annual Report and, in particular, the following principal risks and all of the other specific factors described in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K before deciding whether to invest in our company.

- We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.
- Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.
- Our strategic realignment and the associated headcount reduction have and are expected to significantly change our business, result in significant expense, may not result in anticipated savings, and will disrupt our business.
- We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.
- We need to scale our infrastructure in advance of demand for our tests and other services, and our failure to generate sufficient demand for our tests and other services would have a negative impact on our business and our ability to attain profitability.
- The global macroeconomic environment could negatively impact our business, our financial position and our results of operations.
- We face risks related to health epidemics, including the ongoing COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.
- If third-party payers, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.
- We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the markets in which we operate. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.
- The market for patient data software is competitive, and our business will be adversely affected if we are unable to successfully compete.
- Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- If we are not able to continue to generate substantial demand for our tests, our commercial success will be negatively affected.
- Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.
- Impairment in the value of our goodwill or other intangible assets has and may in the future have a material adverse effect on our operating results and financial condition.
- We have a large amount of debt, servicing our debt requires a significant amount of cash, we may not have sufficient cash flow from our business to service our debt, and we may need to refinance all or a significant portion of our debt.
- If the U.S. Food and Drug Administration ("FDA") regulates the tests we currently offer as laboratory-developed tests ("LDTs") as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.
- One of our competitors has alleged that our Anchored Multiplex PCR, or AMP, chemistry and products using AMP are infringing on its intellectual property, and we may be required to redesign the technology, obtain a license, cease using the AMP chemistry altogether and/or pay significant damages, among other consequences, any of which would have a material adverse effect on our business as well as our financial condition and results of operations.

PART I

ITEM 1. Business

Overview

Invitae is in the business of delivering genetic testing services, digital health solutions and health data services that support a lifetime of patient care and improved outcomes. We offer genetic testing across multiple clinical areas, including hereditary cancer, precision oncology, women's health, rare diseases and pharmacogenomics. Invitae applies proprietary design, process automation, robotics and bioinformatics software solutions to expand the use and impact of genetic information and achieve efficiencies in sample processing and complex variant interpretation, allowing medical interpretation at scale. The result is a new and simplified process for obtaining and using affordable, high-quality genetic information to inform critical healthcare decisions. We also utilize digital health solutions to improve ease-of-use and to deliver actionable information about risk, prevention, treatment, and monitoring. As of December 31, 2022, we have served over 3.6 million patients, and over 2.2 million of those patients have made their information available for data sharing. We believe the depth of our genetic data, along with our approach to combine genetic testing information with third-party patient data, produce an enriched dataset that could lead to valuable insights and benefits to the lives of patients and their families and to the healthcare ecosystem, including providers, biopharma partners, patient advocacy groups and more. Our access and scale enables genomic information to speed the discovery and development of new personalized medical therapies — all while making clinical genetic testing and new solutions available to billions of people.

By pioneering new ways of sharing, understanding and applying genetic information, Invitae is transforming the field of genetics and the application of healthcare data from a series of one-time, one-dimensional queries to a lifelong clinical dialogue with our genes.

Mission and strategy

Invitae's mission is to bring comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people.

We were founded on four core principles:

- Patients should own and control their own genetic information;
- Healthcare professionals are fundamental in ordering and interpreting genetic information;
- Driving down the price of genetic information will increase its clinical and personal utility; and
- Genetic information is more valuable when shared.

Our strategy for long-term, profitable growth centers on seven key drivers of our business, which we believe work in conjunction to create a flywheel effect extending our leadership position in the new market we are building:



Those key drivers include:

- **Customer experience:** We see customer experience for patients, providers, and partners as integral to our long-term growth strategy and as an under-utilized catalyst to move genetics into mainstream medicine. Our view is that providing great service and enabling "ease-of-use", such as efficient ordering, comprehensive choices, and reliable turnaround time, are especially important for physicians.
- **Adoption:** As we improve customer experience, we expect more physicians would be open and more willing to increase genetic information in their practice. This is particularly true in fostering adoption among non-genetic experts, who are often the first contact for patients in a health journey. This work will be in parallel with our efforts in producing research supporting guideline expansion and broader advocacy for the benefits of genetic testing.
- **Attract partners:** As we continue to gain adoption and expand our reach, our value proposition to potential partners should increase. These include patient advocacy groups, biopharma partners that utilize our data, testing, network, and services, as well as health systems that intend to implement comprehensive precision medicine.
- **Insights and solutions:** In parallel with bringing new tools and products to the market, our unique capability to combine phenotypic and genotypic data, through both our genetic testing and third-party patient data, we believe produces a rich dataset that is highly attractive to biopharma partners, patient advocacy groups and more. Our services allow our partners to be more precise and move faster with their efforts, such as identifying and recruiting patients, enabling Investigational New Drug (IND) filings, structuring clinical trials, and eventually bringing new therapies to market.
- **Lower cost and higher reimbursement:** As our network continues to scale, we expect to lower our costs and increase our margin, while continuing our pursuit of low prices to drive accessibility and affordability of genetic information. Our ability to sustainably lower our prices is also expected to be balanced by our success in improving reimbursements and cash collection. Through the generation of scientific evidence and proactive engagement with stakeholders, we intend to pursue better payment and additional coverage.
- **Affordability and accessibility:** As we progress, we can continue to drive down prices, yielding more affordability and accessibility of our products for more patients.
- **More patients served:** All of these efforts should compound upon each other, expanding our reach and increasing the value of each offering, ultimately serving more patients.

Ultimately, we anticipate more solutions to further improve customer experiences, which in turn feed more answers for patients, foster greater adoption, and bring on more partners to create a flywheel effect.

Business overview

We are focused on making comprehensive, high-quality medical genetic information more accessible and instrumental to the healthcare ecosystem and stakeholders, including patients, healthcare providers, payers, biopharma partners, patient advocacy groups and more. Medical genetics is central to health outcomes and we are working to bring it to the mainstream by enhancing the customer experience, lowering costs, removing barriers to adoption, and expanding insights and solutions. Ultimately, we expect the utility of the accumulated data will compound, enabling improved individual and population health and advancing the benefits of molecular medicine around the globe.

As we grow, we expect that our business will expand and evolve in three stages:

- 1) **One patient, one test:** We first launched in November 2013 with an offering of approximately 200 genes, growing the test menu over time to include more than 20,000 genes. In 2022, we processed billable volume of 1,290,000 units and generated revenue of \$516.3 million compared to 1,169,000 units and \$460.4 million 2021 billable volume and revenue, respectively.
- 2) **One patient, multiple insights:** We utilize digital health solutions to deliver actionable information about risk, prevention, treatment, and monitoring. With integration, connectivity, and refined go-to-market strategies, we are shifting to a scenario where each patient test provides many opportunities to deliver solutions — for them, for their families and for others in the ecosystem. Our comprehensive portfolio is expected to enable precision medicine, and provide multiple insights for patients as they engage with us across different stages in life and through different health needs. As of December 31,

2022, we have served over 3.6 million patients, and information from over 2.2 million of those patients is available for data sharing.

- 3) **Many patients, many solutions:** Each patient engagement generates data and insights. Aggregating these into solutions for key stakeholders including patients, providers, policymakers, biopharma partners, advocacy groups and others is where we expect the next phase of transformation will occur. We are focusing our efforts on partnering with these stakeholders to advance the development and utility of our platform. Our real-world data is patient-owned and controlled; and our goal is to enable and build a data and patient network through which individuals and partners can access, aggregate, and customize genetic information to further research and create better outcomes. We expect this to allow for the collective insights from many patients to provide multiple solutions for multiple use cases and customer types.

In addition to investing in informatics solutions and infrastructure to support our data and patient network development, we have been expanding our strategic partnerships, which as of December 31, 2022 numbered more than 100 leading biopharmaceutical companies supporting improved patient diagnosis, clinical trial recruitment and other research-related initiatives.

In addition, our biopharmaceutical industry partnerships are complemented by partnerships with leading health systems, executive health programs and leading research institutions, including The Christ Hospital Health Network, the Cleveland Clinic, the Geisinger Health System, the Mayo Clinic, Memorial Sloan Kettering Cancer Center, MedCan, and Stanford Health Care, among others.

Competition

Our competitors include companies that offer molecular genetic testing and consulting services, including specialty and reference laboratories that offer traditional single- and multi-gene tests and biopharmaceutical companies. Principal competitors include companies such as Ambry Genetics Corporation ("Ambry Genetics"), a subsidiary of Realm IDx, Inc. ("Realm IDx"); Athena Diagnostics, Inc. ("Athena Diagnostics") and Blueprint Genetics, subsidiaries of Quest Diagnostics Incorporated ("Quest Diagnostics"); Baylor-Miraca Genetics Laboratories LLC ("Baylor-Miraca Genetics Laboratories"); Caris Life Sciences, Inc. ("Caris Life Sciences"); Centogene AG; Color Health, Inc. ("Color Health"); Connective Tissue Gene Test LLC ("Connective Tissue Gene Test"), a subsidiary of Health Network Laboratories, L.P. ("Health Network Laboratories"); Cooper Surgical, Inc. ("Cooper Surgical"); Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Exact Sciences Corporation ("Exact Sciences"); Foundation Medicine, Inc. ("Foundation Medicine"), a subsidiary of Roche Holding AG; Fulgent Genetics, Inc. ("Fulgent Genetics"); GeneDx Holdings Corp ("GeneDx Holdings"); Guardant Health, Inc. ("Guardant Health"); Integrated Genetics, Sequenom Inc. ("Sequenom"), Correlagen Diagnostics, Inc. ("Correlagen Diagnostics"), and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings ("Labcorp"); Myriad Genetics, Inc. ("Myriad Genetics"); Natera, Inc. ("Natera"); NeoGenomics, Inc. ("NeoGenomics"); Perkin Elmer, Inc. ("Perkin Elmer"); and Tempus Labs, Inc. ("Tempus Labs") as well as other commercial and academic laboratories.

In addition, there are a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness, including Illumina, Inc. ("Illumina") which is also one of our suppliers. In addition to the companies that currently offer traditional genetic testing services and research centers, other established and emerging healthcare, information technology and service companies may commercialize competitive products including informatics, analysis, integrated genetic tools and services for health and wellness.

We believe the principal competitive factors in our market are:

- comprehensive content;
- quality;
- reliability;
- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;
- ease-of-use and convenience of testing;
- brand recognition of test provider;
- additional value-added services and informatics tools;

- client service; and
- quality of website content.

We believe that we compare favorably with our competitors on the basis of these factors. However, certain competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration in certain testing categories, substantially greater financial, technological and research and development resources, selling and marketing capabilities, and/or more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests, or sell their tests at prices designed to win significant levels of market share. We may compete less effectively against these organizations in some areas of testing.

Regulation

Reimbursement

Under the Protecting Access to Medicare Act of 2014 (as amended), or PAMA, and its implementing regulations, laboratories that realize at least \$12,500 in Medicare Clinical Laboratory Fee Schedule, or CLFS, revenues during the six-month reporting period and that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule must report, beginning in 2017, and then in 2024 and every three years thereafter (or annually for “advanced diagnostic laboratory tests”), private payer payment rates and volumes for their tests. We do not have advanced diagnostic laboratory test status for our tests, and therefore believe we are required to report private payer rates for our tests on an every three-years basis starting next in 2024. Centers for Medicare & Medicaid Services, or CMS, uses the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil money penalties.

Since January 1, 2018, Medicare payments for clinical diagnostic laboratory tests have been paid based upon these reported private payer rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the cross-walk or gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test.

Where applicable, reductions to payment rates resulting from the new methodology were limited to 10% per test per year in each of the years 2018 through 2020. Rates were held at 2020 levels during 2021 and 2022 and will continue to be held at such levels in 2023. Then, where applicable based upon median private payer rates reported in 2017 or 2024, payment rates may be reduced by up to 15% per test per year in each of 2024 through 2026 (with a second round of private payer rate reporting in 2024 to establish rates for 2025 through 2027).

PAMA codified Medicare coverage rules for laboratory tests by requiring any local coverage determination to be made following the local coverage determination process. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory-specific Medicare Administrative Contractors, or MACs. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate. It is unclear whether CMS will proceed with contractor consolidation under this authorization.

PAMA also authorized the adoption of new, temporary billing codes and/or unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The American Medical Association has created a new section of billing codes, Proprietary Laboratory Analyses, or PLAs, to facilitate implementation of this section of PAMA. These codes may apply to one or more of our tests if we apply for PLA coding.

CMS maintains a national coverage determination, or NCD, for next generation sequencing, or NGS, tests for somatic (acquired) and germline (inherited) cancer testing. For somatic cancer testing, the NCD establishes national Medicare coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays that report results using report templates that specify treatment options when offered for their FDA-approved or FDA-cleared use(s), ordered by the patient’s treating physician for Medicare beneficiaries with advanced cancer (recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer) who have not have previously been tested with the same test using NGS for the same cancer genetic content, and have decided to seek further cancer treatment (e.g., therapeutic chemotherapy). The NCD also gives MACs the authority to establish local coverage for NGS-based somatic cancer assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It appears that NGS-based somatic cancer tests provided for

patients with cancer that do not meet the above-referenced criteria, e.g., patients with earlier stage cancers, are currently nationally non-covered under the NCD.

The NCD also establishes national Medicare coverage for FDA-approved or FDA-cleared NGS-based germline tests that report results using report templates that specify treatment options when ordered by the patient's treating physician for patients with ovarian or breast cancer, a clinical indication for germline testing for hereditary breast or ovarian cancer, and a risk factor for germline breast or ovarian cancer, provided the patient has not previously been tested with the same germline test using NGS for the same germline genetic content. The NCD also gives MACs the authority to establish local coverage for NGS-based germline tests for ovarian or breast cancer that are not FDA-approved or FDA-cleared, as well as for NGS-based tests for any other cancer diagnosis (regardless of the test's FDA regulatory status) when offered to patients meeting the above-referenced criteria for germline testing. Since we already have local coverage for our germline tests for ovarian and breast cancer, we believe that the NCD will not have a material impact on which of our tests will be reimbursable by CMS for Medicare patients.

Clinical Laboratory Improvement Amendments of 1988, or CLIA

Our clinical reference laboratories in California, North Carolina and New Jersey are required to hold certain federal certificates to conduct our business. Under CLIA, we are required to hold certificates applicable to the type of laboratory examinations we perform and to comply with standards covering personnel, facilities administration, inspections, quality control, quality assurance and proficiency testing.

We have current certifications under CLIA to perform testing at our laboratory locations in California, North Carolina, and New Jersey. To renew our CLIA certifications, we are subject to survey and inspection every two years to assess compliance with program standards. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

If our clinical reference laboratories are out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificates, as well as directed plan of correction, state on-site monitoring, significant civil money penalties, civil injunctive suit or criminal penalties. We must maintain CLIA compliance and certifications to be eligible to bill for diagnostic services provided to Medicare and Medicaid beneficiaries. If we were to be found out of compliance with CLIA requirements and subjected to sanction, our business could be harmed.

State laboratory licensure requirements

We are required to maintain in-state licenses to conduct testing in California, New Jersey and Washington. California, New Jersey and Washington laws establish standards for day-to-day operations of our laboratories in those states. Such laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratories. If our clinical reference laboratories are out of compliance with applicable standards, the appropriate state agency may suspend, restrict or revoke our licenses to operate our clinical reference laboratories, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business. We maintain current licenses in good standing. However, we cannot provide assurance that state regulators will at all times in the future find us to be in compliance with all such laws.

Several states require the licensure of out-of-state laboratories that accept specimens from those states. Our California laboratory holds the required out-of-state laboratory licenses for Maryland, New York, Pennsylvania, and Rhode Island. Our Washington, North Carolina and New Jersey laboratories hold the required out-of-state laboratory licenses in California, Maryland, New York, Pennsylvania, and Rhode Island.

In addition to having laboratory licenses in New York, our clinical reference laboratories are also required to obtain approval on a test-specific basis for the tests they run as LDTs by the New York State Department of Health, or NYDOH, before specific testing is performed on samples from New York.

Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of human blood or saliva necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States.

Federal oversight of laboratory developed tests

We provide many of our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by CLIA and state law, respectively).

Historically, the U.S. Food and Drug Administration, or FDA, has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality system regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. For example, in 2014, the FDA issued two draft guidance documents that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. These documents have not been finalized to date.

Subsequently, in August 2020, the U.S. Department of Health and Human Services – the parent agency for FDA – announced that the FDA “will not require premarket review of LDTs absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances.” In November 2021, the Biden Administration rescinded this policy.

At this time, it is unclear when, or if, the FDA will finalize its plans to end enforcement discretion (e.g., via notice and comment rulemaking or otherwise), and even then, the new regulatory requirements are expected to be phased-in over time. Nevertheless, the FDA may attempt to regulate certain LDTs on a case-by-case basis at any time.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time-to-time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time.

If the FDA ultimately regulates certain LDTs, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition, and results of operations.

Notwithstanding the FDA's current position with respect to oversight of our LDTs, we may voluntarily decide to pursue FDA pre-market review for our current LDTs and/or LDTs we may offer in the future if we determine that doing so would be appropriate from a strategic perspective – e.g., if CMS indicated that it no longer intended to cover tests offered as LDTs.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

Medical device regulatory framework

Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act, or FDCA, the FDA has jurisdiction over medical devices, which are defined to include, among other things, in vitro diagnostics, or IVDs. The FDA regulates the research, design, development, pre-clinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Specifically, for the tests we may offer in the future that FDA regulates as a device, and if the FDA begins to actively regulate LDTs, then for those tests as well, each new or significantly modified test we seek to commercially distribute in the United States could require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a premarket approval, or PMA,

application, unless an exemption applies. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Device classification

Under the FDCA, medical devices are classified into one of three classes (Class I, Class II or Class III) depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to General Controls for Medical Devices, which require compliance with the applicable portions of the FDA's Quality System Regulation, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. While some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below, most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These Special Controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review by the FDA. Premarket review by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk, such as life-supporting, life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent to a legally-marketed predicate device. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The 510(k) clearance process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics, but the information submitted demonstrates that the device is as safe and effective and does not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) premarket notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including data from samples collected in a clinical setting, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III because there is no available predicate device, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the De Novo classification process. The De Novo classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A

manufacturer can submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents moderate or low risk. De Novo classification may also be available after receipt of a “not substantially equivalent” letter following submission of a 510(k) to FDA.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer’s determination. Many minor modifications are accomplished by an internal letter-to-file in which the manufacturer documents its reasoning for why a change does not require premarket submission to the FDA. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters-to-file in an inspection. If the FDA disagrees with a manufacturer’s determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

The PMA approval process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant’s response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee’s recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA’s satisfaction;
- the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA clearance or approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval order, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval order authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA’s evaluation of a PMA application or manufacturing facility is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data are submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA

application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. New PMA applications or PMA supplements may also be required for modifications to any approved diagnostic tests, including modifications to manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

The investigational device process

In the United States, absent certain exceptions, human clinical trials intended to support the safety and effectiveness of a medical device to obtain FDA clearance or approval require an investigational device exemption, or IDE, application. Investigations that meet certain requirements – i.e., involve tests that are labeled investigational use only (IUO), are noninvasive, do not require an invasive sampling procedure that presents significant risk, do not by design or intention introduce energy into a subject, and are not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established product or procedure — are exempt from the IDE requirement. Some types of studies deemed to present “non-significant risk” are deemed to have an approved IDE — without affirmative submission of an IDE application to the FDA — once certain requirements are addressed and Institutional Review Board, or IRB, approval is obtained. If the device presents a “significant risk” to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials.

Where applicable, the IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Such clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA for any clinical trials subject to FDA oversight. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a 510(k) premarket notification, for numerous reasons.

The Breakthrough Devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, provided the device also represents breakthrough technology, is one for which no approved or cleared treatment exists, offers significant advantages over existing approved or cleared alternatives, or is one whose availability is in the best interest of patients. All submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed. Although Breakthrough Device designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory clearance or approval for such product.

Post-market regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of “off-label” uses of cleared or approved products;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA’s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- requesting or requiring recalls, withdrawals, or administrative detention or seizure of our products;
- imposing operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

HIPAA and state privacy, security and breach notification laws

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, the U.S. Department of Health and Human Services issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and requirements for protecting the privacy and security of protected health information, or PHI, used or disclosed by covered entities, including most health care providers and their respective business associates, as well as the business associates’ subcontractors. We are required to comply with the provisions of HIPAA and HITECH and the regulations implemented thereunder setting forth standards for the privacy of PHI; security standards for the protection of electronic PHI; breach notification requirements; and standards for electronic transactions, which establish standards for common healthcare transactions.

The HIPAA privacy regulations establish requirements and restrictions for the use and disclosure of PHI by covered entities as well as business associates, which are persons or entities that perform certain functions for or on behalf of a covered entity that involve the creation, receipt, maintenance, or transmittal of PHI. Business associates are defined to include a subcontractor to whom a business associate delegates a function, activity, or service, other than in the capacity of the business associate's workforce. As a general rule, a covered entity or business associate may not use or disclose PHI except as permitted or required under the privacy regulations. The privacy regulations also grant certain rights to individuals with respect to their PHI, including the right to access and amend certain records containing their PHI, request restrictions on the use or disclosure of their PHI, and request an accounting of disclosures of their PHI.

Covered entities and business associates also must comply with the HIPAA security regulations, which establish requirements for safeguarding the confidentiality, integrity, and availability of PHI that is electronically transmitted or electronically stored. The HIPAA security regulations include requirements for implementing workforce training, implementing policies, and conducting an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic PHI maintained by the covered entity or business associate.

In addition, covered entities and business associates must comply with certain breach notification requirements. In the event of a breach of unsecured PHI, a covered entity must notify any affected individual, the Secretary of the U.S. Department of Health and Human Services and, under certain circumstances, the media. A business associate must notify the relevant covered entity of any breach of unsecured PHI.

Penalties for failure to comply with a requirement of HIPAA or HITECH vary significantly, and, depending on the knowledge and culpability of the HIPAA-regulated entity, may include civil monetary penalties of up to \$1.9 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to \$50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. A covered entity or business associate may also be liable for civil money penalties for a violation that is based on an act or omission of any of its agents as determined according to the federal common law of agency, which may include a business associate or subcontractor business associates. Complying with HIPAA and HITECH requires significant resources, and we may be restricted in our ability to perform certain activities that involve the collection, use, or disclosure of PHI due to the limitations in the HIPAA privacy regulations. Additionally, to the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

The HIPAA and HITECH privacy, security, and breach notification regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or insofar as such state laws apply to personal information that is broader in scope than PHI as defined under HIPAA. Massachusetts, for example, has a state law that protects the privacy and security of personal information of Massachusetts residents. In addition, every U.S. state has a data breach notification law that requires entities to report certain security breaches to affected consumers and, in some instances, state regulators and consumer reporting agencies. Many states also have laws or regulations that specifically apply to genetic testing and genetic information and are more stringent than the standards under HIPAA. These state genetic information privacy laws include specific informed consent requirements for the conduct of genetic testing and restrict the collection, use, disclosure, or retention of genetic information. Failure to comply with applicable state laws that impose privacy, security, or breach notification requirements for genetic or other personal information could result in significant civil or criminal penalties, administrative actions, or private causes of action by patients, and adversely affect our business, results of operations and reputation.

Federal and state consumer protection laws

The Federal Trade Commission, or FTC, is an independent U.S. law enforcement agency charged with protecting consumers and enhancing competition across broad sectors of the economy. The FTC has indicated that it will be considering new data privacy regulations, which, if adopted, could impact our operations if they impose substantial new obligations or restrictions with respect to our data collection and processing activities. The FTC's primary legal authority with respect to data privacy and security comes from Section 5 of the FTC Act, which prohibits unfair or deceptive acts or practices in the marketplace. The FTC uses this broad authority to police data privacy and security, using its powers to investigate and bring lawsuits. Where appropriate, the FTC can seek a variety of remedies, such as but not limited to requiring the implementation of comprehensive privacy and security

programs, biennial assessments by independent experts, monetary redress to consumers, and provision of robust notice and choice mechanisms to consumers. In addition to its enforcement mechanisms, the FTC uses a variety of tools to protect consumers' privacy and personal information, including pursuing enforcement actions to stop violations of law, conducting studies and issuing reports, hosting public workshops, developing educational materials, and testifying before the U.S. Congress on issues that affect consumer privacy. The FTC has become more aggressive in its enforcement actions against not only companies, but individual executives as well. To the extent that individual executives become subject to an FTC consent decree, or that an executive subject to a consent decree joins our company, it could impact our operations.

The vast majority of data privacy cases brought by the FTC fall under the "deceptive" acts prong of Section 5. These cases often involve a failure on the part of a company to adhere to its own privacy and data protection principles set forth in its policies. To avoid Section 5 violations, the FTC encourages companies to build privacy protections and safeguards into relevant portions of their business, and to consider privacy and data protection as the company grows and evolves. In addition, privacy notices should clearly and accurately disclose the type(s) of personal information the company collects, how the company uses and shares that information, and the security measures used by the company to protect that information.

In recent years, the FTC's enforcement under Section 5 related to data security has included alleged violations of the "unfairness" prong. Many of these cases have alleged that companies were unfair to consumers because they failed to take reasonable and necessary measures to protect consumer data, and especially, data that the FTC considers sensitive, such as geolocation data. The FTC has not provided bright line rules defining what constitutes "reasonable and necessary measures" for implementing a cybersecurity program, but it has provided guidance, tips and advice for companies. The FTC has also published past complaints and consent orders, which it urges companies use as guidance to help avoid an FTC enforcement action, even if a data breach or loss occurs.

In addition to the FTC Act, most U.S. states have unfair and deceptive acts and practices statutes, known as UDAP statutes, that substantially mirror the FTC Act and have been applied in the privacy and data security context. These UDAP statutes vary in substance and strength from state to state. Many have broad prohibitions against unfair and deceptive acts and practices. These statutes generally allow for private rights of action and are enforced by the states' Attorneys General.

State Consumer Privacy Legislation

The California Consumer Privacy Act, or CCPA, is a comprehensive consumer privacy law that took effect on January 1, 2020 and was further amended as of January 1, 2023. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of natural persons who reside in California. Among other things, the CCPA confers to California residents the rights of data transparency, access, deletion, correction, and the ability to opt-out of or limit the use of their personal data for certain purposes. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure.

The CCPA does not apply to personal information that is PHI under HIPAA. The CCPA also does not apply to a HIPAA-regulated entity to the extent that the entity maintains patient information in the same manner as PHI. In addition, de-identified data as defined under HIPAA is also exempt from the CCPA. Accordingly, we do not have CCPA compliance obligations with respect to most genetic testing and patient information we collect and process. However, we are required to comply with the CCPA insofar as we collect other categories of California consumers' personal information.

Several states have passed consumer privacy legislation that is substantially similar to the CCPA and will take effect in 2023. The Colorado Privacy Act will take effect on July 1, 2023; the Connecticut Personal Data Privacy Act will take effect on July 1, 2023; the Utah Consumer Privacy Act will take effect on December 31, 2023, and the Virginia Consumer Data Protection Act came into effect on January 1, 2023. Each of these state laws provides substantially the same rights to residents of each respective state as does the CCPA for California residents. Unlike the CCPA, however, each of these other state laws excludes information collected from employees or business-to-business contacts. Each of the laws also do not apply to PHI under HIPAA and also generally exempt HIPAA-regulated entities from their reach. The state laws are enforced by their respective state's Attorney Generals, and none of them includes a private right of action.

Dozens of other states in the United States are currently considering similar consumer data privacy laws, which could impact our operations if enacted.

Privacy and data protection laws

There are a growing number of jurisdictions around the globe that have privacy and data protection laws that may apply to Invitae as it enters or expands its business in jurisdictions outside of the United States. These laws are typically triggered by a company's establishment or physical location in the jurisdiction, data processing activities that take place in the jurisdiction, and/or the processing of personal information about individuals located in that jurisdiction. Certain international privacy and data protection laws, such as those in the European Union (EU), are more restrictive and proscriptive than those in the U.S., while other jurisdictions may have laws less restrictive or proscriptive than those in the U.S. Enforcement of these laws varies from jurisdiction to jurisdiction, with a variety of consequences, including civil or criminal penalties, litigation, private rights of action or damage to our reputation.

Europe

The EU's General Data Protection Regulation, or GDPR, took effect on May 25, 2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. The GDPR imposes strict requirements on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, which includes sensitive information such as health and genetic information of data subjects. The GDPR also grants individuals various rights in relation to their personal data, including the rights of access, rectification, objection to certain processing and deletion. The GDPR provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, may result in significant administrative fines issued by EU regulators. Maximum penalties for violations of the EU GDPR are capped at 20 million euros or 4% of an organization's annual global revenue, whichever is greater.

Australia

Australia's federal Privacy Act 1988, or the Privacy Act, and the 13 Australian Privacy Principles, or the APPs, contained in the Privacy Act, apply to government agencies and private sector organizations with annual turnover exceeding AU \$3 million. The Privacy Act extends to all of Australia's external territories, but also applies to an act done, or practice engaged in, or outside Australia (and Australia's external territories) by an organization, or small business operator, that has a link to Australia, such as a continued presence, partnership, incorporation, central management and control, or citizenship in Australia. An organization may also have a link to Australia if the organization conducts business in Australia and collects or stores personal information in Australia. The Privacy Act applies to any collection, holding, use or disclosure of personal information by a regulated entity, with enhanced protections for sensitive information such as genetic information. The Privacy Act prescribes certain rights for individuals, including rights to know why the information is collected, how it is used, and to whom it is disclosed, the right of the individual not to identify themselves in certain circumstances, the right of access, the right to stop receiving unwanted direct marketing, the right to correct information, and the right to make a complaint. Australia's Privacy Commissioner enforces the Privacy Act and any acts that may violate an individual's privacy. The Privacy Commissioner can levy significant fines on individuals and corporations that violate the Privacy Act.

Canada

Canada has several federal, provincial and territorial privacy statutes that govern the protection of personal information. The Personal Information Protection and Electronic Documents Act 2000, or PIPEDA, applies to the collection, use, and disclosure of personal information in the course of commercial activities in Canada. Although PIPEDA is silent with respect to its extraterritorial application, the Federal Court of Canada has concluded that PIPEDA applies to businesses established in other jurisdictions if there is a "real and substantial connection" between the organization's activities and Canada. PIPEDA and provincial data protection laws require specific notices regarding openness and transparency and require regulated organizations to obtain consent in order to process such information. Canadian individuals enjoy rights or access and to correct inaccuracies. Violations of Canadian data protection laws can result in significant fines. Canada is evaluating replacing or substantially amending PIPEDA so as to make it similar to the GDPR. Such changes to PIPEDA could impact our operations if enacted. Canada is considering a series of significant amendments to PIPEDA, the implementation of which would be to make PIPEDA more like GDPR. If the amendments to PIPEDA were to come into effect, they could have an impact on our operations in Canada.

India

The Indian Constitution has been interpreted by India's highest court to include a fundamental right to privacy. In addition, the Information Technology Act 2000, as amended, or the IT Act, is the primary national law regulating the collection and use of personal information that is sensitive. The IT Act applies to corporations and other "body corporates" that possess, maintain, or otherwise process personal information, including body corporates that act on behalf of other body corporates. Certain provisions of the IT Act provide liability for negligent handling of personal information. For example, the IT Act provides that any corporation or other body corporate that handles sensitive personal data is liable to pay damages for any loss caused by its negligence in implementing and maintaining reasonable security practices and procedures.

In addition, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules 2011, or the Data Privacy Rules, issued under the IT Act regulate the use of personal information and sensitive personal data. The Data Privacy Rules mandate that businesses have a privacy policy, obtain consent when collecting or transferring personal information, and inform the data subject about any recipients of that data. The IT Act includes a private right of action for individuals, and authorizes criminal punishment (with a fine, three years in prison, or both) for disclosing personal information without the consent of the data subject or in breach of any relevant contract.

India's parliament is currently evaluating a new data privacy bill that would bear many similarities with GDPR, but that would also contain certain additional requirements including, for example, possible data localization requirements. If enacted, India's new law could impact our operations.

Israel

Israel's data protection regime is governed primarily by the Protection of Privacy Law and the regulations promulgated under it, or the PPL, and the guidelines of the Israeli regulator, the Privacy Protection Authority, or the PPA. The PPL applies to: (1) database owners, database holders, and database managers based in Israel; and (2) data processing operations that take place in Israel, regardless of whether the individuals about whom the data relates are residents or citizens of Israel. The PPL could also be interpreted to apply to non-Israeli database owners, database holders, or database managers that process personal information about Israeli residents or citizens when such processing takes place outside of Israel. Various regulations promulgated under the PPL by the PPA set out rules and procedures for data security, data retention, data subject rights, and cross border transfers of data. These regulations also do not clearly state their jurisdictional scope, such that there is a risk they could be interpreted as applying to foreign-based entities that process data about Israeli citizens.

The PPA is required to maintain a registry of databases and is empowered to supervise compliance with and investigate alleged violations of the PPL and related regulations. The PPA may impose administrative fines for violations of the PPL and related regulations, and willful violations may result in criminal liability and up to five years in prison. A breach of privacy is also actionable, and an individual claimant may obtain monetary compensation or injunctive relief. A court may award statutory damages without proof of damages for breach of privacy rights. If the breach was intentional, the damages may be doubled. The PPL also specifies that an act or omission in breach of certain of its provisions, such as failure to ensure data security, may give rise to a tort claim.

Japan

Japan's primary data protection law, the Act on the Protection of Personal Information was amended in 2020 to include GDPR-like requirements, including additional transparency requirements, data transfer obligations, enhanced data breach notification requirements, additional data subject rights and stronger penalties for violations, including significant fines. The amendment clarifies that its provisions, obligations and penalties apply to entities outside of Japan that supply goods or services in Japan and handle personal information from an individual in Japan. These amendments went into effect on April 1, 2022.

Information blocking prohibition

On May 1, 2020, the Office of the National Coordinator for Health Information Technology promulgated final regulations under the authority of the 21st Century Cures Act to impose new conditions to obtain and maintain certification of certified health information technology and prohibit certain covered actors, including developers of certified health information technology, health information networks / health information exchanges, and health care providers (including laboratories), from engaging in activities that are likely to interfere with the access, exchange, or use of electronic health information (information blocking). The final regulations further defined exceptions for activities that are permissible, even though they may have the effect of interfering with the access, exchange, or use

of electronic health information. The information blocking regulation effective date was April 5, 2021. Under the 21st Century Cures Act, health care providers that violate the information blocking prohibition will be subject to appropriate disincentives, which the U.S. Department of Health and Human Services has yet to establish through required rulemaking. Developers of certified information technology and health information networks / health information exchanges, however, may be subject to civil monetary penalties of up to approximately \$1 million (as adjusted for inflation) per violation. If the government were to conclude that we met the definition of a health information network or health information exchange, we could be potentially subject to such penalties. However, the U.S. Department of Health and Human Services Office of Inspector General has the authority to impose such penalties and on April 24, 2020 published a proposed rule to codify the civil monetary penalty authority in regulation, which the agency proposed would be effective 60 days after it issues a final rule, but in no event before November 2, 2020. The U.S. Department of Health and Human Services Office of Inspector General has not yet issued a final rule.

Federal, state and foreign fraud and abuse laws

In the United States, there are various fraud and abuse laws with which we must comply, and we are potentially subject to regulation by various federal, state and local authorities, including CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, and individual U.S. Attorney offices within the Department of Justice, and state and local governments. We also may be subject to foreign fraud and abuse laws.

In the United States, the federal Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering of any good, facility, service or item for which payment may be made in whole or in part by a federal healthcare program. Many courts have held that the Anti-Kickback Statute may be violated if any one purpose of the remuneration is to induce or reward patient referrals or other federal healthcare program business, regardless of whether there are other legitimate purposes for the arrangement. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, consulting fees, waivers of co-payments, ownership interests, and providing anything at less than its fair market value. The Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry. The Anti-Kickback Statute includes several statutory exceptions, and the U.S. Department of Health and Human Services has issued a series of regulatory "safe harbors." These exceptions and safe harbor regulations set forth certain requirements for various types of arrangements, which, if met, will protect the arrangement from potential liability under the Anti-Kickback Statute. Although full compliance with the statutory exceptions or regulatory safe harbors ensures against liability under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific statutory exception or regulatory safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. Penalties for violations of the Anti-Kickback Statute are severe, and include imprisonment, criminal fines, civil money penalties, and exclusion from participation in federal healthcare programs. Many states also have anti-kickback statutes, some of which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

There are also federal laws related to healthcare fraud and false statements, among others, that apply to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payer programs such as the Medicare and Medicaid programs. The false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payer programs.

Another development affecting the healthcare industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payer program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by presenting or causing to be presented a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims

Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each false claim. For penalties assessed after May 9, 2022, whose associated violations occurred after November 2, 2015, the penalties range from \$12,537 to 25,076 for each false claim. The minimum and maximum per claim penalty amounts are subject to annual increases for inflation.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and some of these state laws apply where a claim is submitted to any third-party payer and not only a governmental payer program.

Additionally, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have knowingly presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or for a claim that is false or fraudulent. This law also prohibits the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for items or services reimbursable by Medicare or a state healthcare program. There are several exceptions to the prohibition on beneficiary inducement.

The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits, among other things, payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs, to include private insurance (i.e., it is an "all payer" statute). For purposes of EKRA, the term "laboratory" is defined broadly and without reference to any connection to substance use disorder treatment. EKRA is a criminal statute and violations can result in fines of up to \$200,000, up to 10 years in prison, or both, per violation. The law includes a limited number of exceptions, some of which closely align with corresponding federal Anti-Kickback Statute exceptions and safe harbors and others that materially differ.

We are also subject to the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. In Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act 2010, faces imprisonment of up to ten years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, also imposed annual reporting requirements on entities including manufacturers of certain devices, medical supplies, drugs and biologics for certain payments and transfers of value that the manufacturer provides, directly or indirectly, to or on behalf of physicians, certain other providers including physician assistants and nurse practitioners, and teaching hospitals. The Physician Payments Sunshine Act also requires entities including applicable manufacturers to report certain ownership and investment interests held by physicians and their immediate family members in such manufacturers. In addition, certain states, such as Vermont and Massachusetts, have enacted laws that impose certain reporting requirements for payments and transfers of value provided to covered healthcare providers. These state laws are not preempted by the federal Physician Payments Sunshine Act to the extent the state law requires the reporting of information that is not required to be reported under the federal Physician Payments Sunshine Act. Finally, certain states such as Massachusetts, Nevada, and Vermont have enacted laws that limit or prohibit the provision of payments or other transfers of value to covered recipients, such as certain health care providers, hospitals, and health benefit plan administrators.

Physician referral prohibitions

A federal law directed at "self-referrals," commonly known as the "Stark Law," prohibits a physician from referring a patient to an entity for certain Medicare-covered designated health services, including laboratory services, if the physician, or an immediate family member, has a financial relationship with the entity, unless an exception applies. The Stark Law also prohibits an entity from billing for services furnished pursuant to a prohibited referral. A physician or entity that engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to \$185,009 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to civil monetary penalties of up to \$27,750 per service, an assessment of up to three times the amount claimed and possible exclusion from

participation in federal healthcare programs. Bills submitted in violation of the Stark Law may not be paid by Medicare, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states have comparable laws that apply to services covered by other third-party payers. The Stark Law also prohibits state receipt of federal Medicaid matching funds for services furnished pursuant to a prohibited referral. This provision of the Stark Law has not been implemented by regulations, but some courts have held that the submission of claims to Medicaid that would be prohibited as self-referrals under the Stark Law for Medicare could implicate the False Claims Act.

Corporate practice of medicine

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging clinicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. For example, California's Medical Board has indicated that determining what diagnostic tests are appropriate for a particular condition and taking responsibility for the ultimate overall care of the patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings.

Intellectual property

We rely on a combination of intellectual property rights, including trade secrets, copyrights, trademarks, customary contractual protections and, to a lesser extent, patents, to protect our core technology and intellectual property. With respect to patents, we believe that the practice of patenting individual genes, along with patenting tools and methods specific to individual genes, has impeded the progress of the genetic testing industry beyond single gene tests and is antithetical to our core principle that patients should own and control their own genomic information. The U.S. Supreme Court has issued a series of unanimous (9-0) decisions setting forth limits on the patentability of natural phenomena, natural laws, abstract ideas and their applications — *i.e.*, *Mayo Collaborative v. Prometheus Laboratories (2012)*, or *Mayo*, *Association for Molecular Pathology v. Myriad Genetics (2013)*, or *Myriad*, and *Alice Corporation v. CLS Bank (2014)*, or *Alice*. As discussed below, we believe the *Mayo*, *Myriad* and *Alice* decisions bring clarity to the limits to which patents may cover specific genes, mutations of such genes, or gene-specific technology for determining a patient's genomic information.

Patents

U.S. Supreme Court cases have clarified that naturally occurring DNA sequences are natural phenomena, which should not be patentable. On June 13, 2013, the U.S. Supreme Court decided *Myriad*, a case challenging the validity of patent claims held by Myriad relating to the cancer genes BRCA1 and BRCA2. The *Myriad* Court held that genomic DNAs that have been isolated from, or have the same sequence as, naturally occurring samples, such as the DNA constituting the BRCA1 and BRCA2 genes or fragments thereof, are not eligible for patent protection. Instead, the *Myriad* Court held that only those complementary DNAs (cDNAs) which have a sequence that differs from a naturally occurring fragment of genomic DNA may be patent eligible. Because it will be applied by other courts to all gene patents, the holding in *Myriad* also invalidates patent claims to other genes and gene variants. Prior to *Myriad*, on August 16, 2012, the U.S. Court of Appeals for the Federal Circuit had held that certain patent claims of Myriad directed to methods of comparing or analyzing BRCA1 and BRCA2 sequences to determine whether or not a person has a variant or mutation are unpatentable abstract processes, and Myriad did not appeal such ruling.

We do not currently have any patents or patent applications directed to the sequences of specific genes or variants of such genes, nor do we rely on any such in-licensed patent rights of any third party. We believe that correlations between specific gene variants and a person's susceptibility to certain conditions or diseases are natural laws that are not patentable under the U.S. Supreme Court's decision in *Mayo*. The *Mayo* case involved patent claims directed to optimizing, on a patient-specific basis, the dosage of a certain drug by measuring its metabolites in a patient. The *Mayo* Court determined that patent claims directed at detection of natural correlations, such as the correlation between drug metabolite levels in a patient and that drug's optimal dosage for such patient, are not eligible for patent protection. The *Mayo* Court held that claims based on this type of comparison between an observed fact and an understanding of that fact's implications represent attempts to patent a natural law and, moreover, when the processes for making the comparison are not themselves sufficiently inventive, claims to such processes are similarly patent-ineligible. On June 19, 2014, the U.S. Supreme Court decided *Alice*, where it amplified its *Mayo* and *Myriad* decisions and clarified the analytical framework for distinguishing between patents

that claim laws of nature, natural phenomena and abstract ideas and those that claim patent-eligible applications of such concepts. According to the *Alice* Court, the analysis depends on whether a patent claim directed to a law of nature, a natural phenomenon or an abstract idea contains additional elements, an “inventive concept,” that “is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself” (citing *Mayo*).

We believe that *Mayo*, *Myriad* and *Alice* not only render as unpatentable genes, gene fragments and the detection of a person’s sequence for a gene, but also have the same effect on generic applications of conventional technology to specific gene sequences. For example, we believe that generic claims to primers or probes directed to specific gene sequences and uses of such primers and probes in determining a person’s genetic information are not patentable. We do not currently have any patents or patent applications directed to such subject matter nor have we in-licensed such patents rights of any third party.

Unlike patents directed to specific genes, we do rely upon, in part, patent protection to protect technology that is not gene-specific and that provides us with a potential competitive advantage as we focus on making comprehensive genetic information less expensive and more broadly available to our customers. In this regard, we have issued U.S. patents, pending U.S. patent applications and corresponding non-U.S. patents and patent applications directed to various aspects of our laboratory, analytic and business practices. We intend to pursue further patent protection where appropriate.

For information regarding legal actions that pertain to intellectual property rights, see Note 8, “Commitments and contingencies” in Notes to Consolidated Financial Statements in Part II, Item 8. of this report.

Trade secrets

In addition to seeking patent protection for some of our laboratory, analytic and business practices, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain and develop our competitive position. We have developed proprietary procedures for both the laboratory processing of patient samples and the analysis of the resulting data to generate clinical reports. For example, we have automated aspects of our processes for curating information about known variants, identifying variants in an individual’s sequence information, associating those variants with known information about their potential effects on disease, and presenting that information for review by personnel responsible for its interpretation and for the delivery of test reports to clinicians and patients. We try to protect these trade secrets, in part, by taking reasonable steps to keep them confidential. This includes entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees and certain third parties. We also enter into invention or patent assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we may not enter into such agreements with all relevant parties, and these parties may not abide by the terms of their agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy or independently develop and commercially exploit aspects of our technology or obtain and use information that we regard as proprietary.

Trademarks

We work hard to achieve a high level of quality in our operations and to provide our customers with a superior experience when interacting with us. As a consequence, our brand is very important to us, as it is a symbol of our reputation and representative of the goodwill we seek to generate with our customers. As a consequence, we have invested significant resources in protection of our trademarks.

Environmental matters

We are committed to maintaining compliance with all environmental laws applicable to our operations and products, and also realize that we need to begin to take steps to address our environmental footprint. We take our responsibility for environmental stewardship seriously and believe that we must do our part in addressing global climate change challenges. While we are early on this journey, we are committed to reducing our environmental impact. We aim to integrate sustainable business practices, energy-efficient technologies and eco-friendly products that advance our progress in reducing our carbon footprint, water consumption and waste.

We realize that our effectiveness in executing upon our environmental objectives first begins with understanding our environmental impact and carbon footprint. We engaged a third-party to complete an in-depth analysis of our 2020, 2021 and 2022 emissions, water and waste data. With this insight, we established a baseline from which to facilitate ongoing internal measuring, managing and reporting of these factors. We believe this

foundation now better positions us to improve internal tracking systems, launch eco-friendly initiatives, normalize our metrics and establish science-based targets to reduce our environmental footprint over time.

Our operations require the use of hazardous materials (including biological materials) that subject us to a variety of federal, state and local environmental and safety laws and regulations. Some of these regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or new regulations will affect our business, operations or the cost of compliance.

Raw materials and suppliers

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Agena Bioscience, Inc., Illumina, Integrated DNA Technologies Inc. ("IDT"), Roche Holdings Ltd., QIAGEN N.V. ("QIAGEN") and Twist Bioscience Corporation for certain laboratory reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We are in active litigation with affiliates of QIAGEN as described in Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Our operations could be interrupted if we encounter delays or difficulties in securing these reagents and enzymes, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our operations, including sequencers and various associated reagents and enzymes. The use of equipment or materials provided by these replacement suppliers would require us to alter our operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot be certain that we will be able to secure alternative equipment, reagents and other materials, or bring such equipment, reagents and materials online and revalidate them without experiencing interruptions in our workflow. If we encounter delays or difficulties in securing, reconfiguring or revalidating equipment and materials, our business and reputation could be adversely affected.

Customer concentration and revenue trends

We receive payment for our products and services from patients, biopharmaceutical partners, third-party payers and other business-to-business customers. As of December 31, 2022, our revenue has been primarily derived from test reports generated from our assays. See information regarding our customer concentration in Note 2, "Summary of significant accounting policies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report.

We have historically experienced higher revenue in our fourth quarter compared to other quarters in our fiscal year due in part to higher demand for our tests from patients who have met their annual insurance deductible. Revenue in the fourth quarter of fiscal year 2022 declined as we exited product offerings and geographies related to our strategic realignment. The continued impact of exiting product offerings and geographies coupled with changes in our product and payer mix might cause these historical trends to be different than future trends of revenue or financial performance.

Human capital resources

Our people

The strength of our team and the culture in which we work is essential to our ability to achieve our broader mission. We had approximately 1,700 employees as of December 31, 2022, of which approximately 61% were women and 39% men. Our management team as of December 31, 2022 was 29% women and 71% men.

Diversity, Equity and Inclusion, or DEI

Our DEI mission is to attract, engage, develop and retain talent from diverse backgrounds by fostering community, providing education and support, and advancing inclusive research and health equity globally. Our vision is to cultivate a place where we all belong. As of December 31, 2022, approximately 56% of our workforce was White, 21% Asian, 9% Hispanic, 5% Black or African American, 4% two or more races (not Hispanic or Latino) and 5% not self-identified based on our payroll system and individual self-identification. On our management team,

21% are people who identify as non-White. With the addition of a board member on January 26, 2023, our board of directors is now 50% racially diverse with 38% female representation and an average age of 58.

Our culture and mission

Our team is driven to make a difference for the patients. We aim to be a highly functioning and collaborative team, well equipped to attract, develop and retain diverse talent while driving culture, engagement, and change management in support of business objectives. Our People & Culture business partners are embedded within leadership teams to help support our talent strategy and team development throughout our organization. We provide employees with opportunities to grow and advance, supported by flexible work hours, flexible paid time off (non-accrual), the ability to work remotely for many roles, and the satisfaction of doing meaningful work.

Our total rewards philosophy

We offer a competitive total rewards package, which includes base compensation, incentive compensation, equity, healthcare coverage, 401(k) (with a partial match), an employee stock purchase plan, and a broad range of other benefits including family leave and parental leave for new parents. Our health vendor provides fertility and adoption benefits for our U.S. employees and most of our global employees. Additionally, we have an employer-sponsored genetic testing program, which provides employees and their covered dependents access to our genetic testing at no cost.

Health and safety

We are committed to maintaining and improving the health and safety of our employees. All employees are responsible for maintaining a safe workplace. We promote, train and ensure employees are following our protocols, rules, policies and practices and are reporting accidents, injuries and unsafe equipment, practices or conditions, in accordance with our Code of Business Conduct and Ethics and health and safety policies. In addition, we established an Enterprise Crisis Management Team that, along with the Employee Health and Safety Administrator, comprise the Steering Committee for pandemic response, which is responsible for ensuring our COVID-19 policies and practices meet all necessary standards and regulations. Our response has evolved as the situation has evolved. We monitor, update and align our corporate policies to meet state and federal occupational health and safety rules. We work to ensure employees follow guidance regarding COVID-19 protocols including testing, quarantine requirements, exposure control measures, contact tracing, and masking.

Information about our executive officers

The names of our executive officers and other corporate officers, and their ages as of February 28, 2023, are as follows:

Name	Age	Position
Executive officers		
Kenneth D. Knight	62	Chief Executive Officer and Director
Yafei (Roxi) Wen	50	Chief Financial Officer
Thomas R. Brida	52	General Counsel, Chief Compliance Officer and Secretary
Robert L. Nussbaum, M.D.	73	Chief Medical Officer
Robert F. Werner	49	Chief Accounting Officer

Kenneth D. Knight has served as a director and our Chief Executive Officer since July 2022. Mr. Knight also served as our Chief Operating Officer from June 2020 to July 2022. Prior to joining Invitae, he most recently served as Vice President of transportation services at Amazon.com, Inc., a multinational and diversified technology company, from December 2019 to June 2020, and as Vice President of Amazon’s global delivery services, fulfillment operations and human resources from April 2016 to December 2019. Prior to his time at Amazon, from 2012 to March 2016, Mr. Knight served as general manager of material handling and underground business division at Caterpillar Inc., a manufacturer of machinery and equipment. Prior to that, Mr. Knight served in various capacities at General Motors Company, a vehicle manufacturer, for 27 years, including as executive director of global manufacturing engineering and as manufacturing general manager. Mr. Knight holds a B.S. in Electrical Engineering from the Georgia Institute of Technology and an M.B.A. from the Massachusetts Institute of Technology.

Yafei (Roxi) Wen has served as our Chief Financial officer since June 2021. Prior to joining Invitae, from February 2019 to June 2021, she served as the Chief Financial Officer at Mozilla Corporation, an open-source software company, overseeing finance and accounting, mergers and acquisitions, business development, data and

analytics, information technology and engineering operations, workplace resources and sustainability. Prior to Mozilla, Roxi served as the Chief Financial Officer at Elo Touch Solutions, a touch screen systems and components company, from April 2014 to February 2019, and General Electric Critical Power, an electronics power technology company, from 2008 to 2013, following her experience driving capital market and business finance efforts at Medtronic, a leading medical technology company, from 2002 to 2008. Roxi is a CFA charterholder and has an M.B.A. from the University of Minnesota.

Thomas R. Brida has served as our General Counsel since January 2017, our Chief Compliance Officer since February 2019, and our Secretary since May 2019. Mr. Brida also served as our Deputy General Counsel from January 2016 to January 2017. Prior to joining Invitae, he was Associate General Counsel at Bio-Rad Laboratories, a life science research and clinical diagnostics manufacturer, from January 2004 to January 2016. He holds a B.A. from Stanford University and a J.D. from the U.C. Berkeley School of Law.

Robert L. Nussbaum, M.D. has served as our Chief Medical Officer since August 2015. From April 2006 to August 2015, he was chief of the Division of Genomic Medicine at UCSF Health where he also held leadership roles in the Cancer Genetics and Prevention Program beginning in January 2009 and the Program in Cardiovascular Genetics beginning in July 2007. From April 2006 to August 2015, he served as a member of the UCSF Institute for Human Genetics. Prior to joining UCSF Health, Dr. Nussbaum was chief of the Genetic Disease Research Branch of the National Human Genome Research Institute, one of the National Institutes of Health, from 1994 to 2006. He is a member of the National Academy of Medicine and a fellow at the American Academy of Arts and Sciences. Dr. Nussbaum is a board-certified internist and medical geneticist who holds a B.S. in Applied Mathematics from Harvard College and an M.D. from Harvard Medical School in the Harvard-MIT joint program in Health Sciences and Technology. He completed his residency in internal medicine at Barnes-Jewish Hospital and a fellowship in medical genetics at the Baylor College of Medicine.

Robert F. Werner has served as our Chief Accounting and Principal Accounting Officer since May 2020. Prior to that, Mr. Werner served as our Corporate Controller from September 2017. Prior to joining Invitae, from February 2015 to September 2017, Mr. Werner served as Vice President of Finance and Corporate Controller of Proteus Digital Health, Inc., a digital medicine pharmaceuticals company. Prior to that, Mr. Werner served as Corporate Controller and Principal Accounting Officer of CardioDx, Inc., a molecular diagnostics company, from March 2012 to February 2015. Mr. Werner is a Certified Public Accountant in California and started his career at Ernst & Young LLP. Mr. Werner holds a B.S. in Accounting and a Master of Accountancy in Professional Accounting from Brigham Young University's Marriott School of Management.

General Information

We were incorporated in the State of Delaware on January 13, 2010 under the name Locus Development, Inc. and changed our name to Invitae Corporation in 2012.

Our principal executive offices are located at 1400 16th Street, San Francisco, California 94103, and our telephone number is (415) 374-7782. Our website address is www.invitae.com. The information contained on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

We make available free of charge on our website our Annual Reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC. You may obtain a free copy of these reports in the Investor Relations section of our website, www.invitae.com. All reports that we file are also available at www.sec.gov.

ITEM 1A. Risk Factors

Risks related to our business and strategy

We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.

We have incurred substantial losses since our inception. For the years ended December 31, 2022, 2021 and 2020, our net losses were \$3.1 billion, \$379.0 million and \$602.2 million, respectively. At December 31, 2022, our accumulated deficit was \$4.8 billion. We expect to continue to incur significant losses as we invest in our business. We incurred research and development expenses of \$402.1 million, \$416.1 million and \$240.6 million and selling and marketing expenses of \$218.9 million, \$225.9 million and \$168.3 million in 2022, 2021 and 2020, respectively. Since 2021, widespread inflationary pressures were experienced across global economies, resulting in higher costs for our raw materials, non-material costs, labor and other business costs, and significant increases in the future could adversely affect our results of operations. In addition, as a result of the integration of acquired businesses, we may be subject to unforeseen or additional expenditures, costs or liabilities, including costs and potential liabilities associated with litigation. Our prior losses and expected future losses have had and may continue to have an adverse effect on our stockholders' equity, working capital and stock price. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We began operations in January 2010 and commercially launched our initial assay in late November 2013. Our prospects must be considered in light of the risks and difficulties frequently encountered by companies in a similar stage of development, particularly companies in new and rapidly evolving markets such as ours. These risks include an evolving and unpredictable business model and the management of growth. To address these risks, we must, among other things, increase our customer base; continue to implement and successfully execute our business and marketing strategy; successfully enter into other strategic collaborations or relationships; obtain access to capital on acceptable terms and effectively utilize that capital; identify, attract, hire, retain, motivate and successfully integrate employees; continue to expand, automate and upgrade our laboratory, technology and data systems; obtain, maintain and expand coverage and reimbursement by healthcare payers; obtain and maintain sufficient payment by partners, institutions and individuals; provide rapid test turnaround times with accurate results at low prices; provide superior customer service; and respond to competitive developments. We cannot assure you that we will be successful in addressing these risks, and the failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.

We expect we will need to raise additional capital to finance operations prior to achieving profitability, or should we make additional acquisitions. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. In addition, the terms of our credit agreement restrict our ability to incur certain indebtedness and issue certain equity securities. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings, if available, could impose significant restrictions on our operations.

The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire companies or acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, selling and marketing initiatives, or potential acquisitions. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to our company.

Our strategic realignment and the associated headcount reduction have and are expected to significantly change our business, result in significant expense, may not result in anticipated savings, and will disrupt our business.

On July 18, 2022, we initiated a strategic realignment of our operations and began implementing programs to reduce operating costs and drive future growth aligned with our core genetic testing and data platform and patient network. This realignment involves a significant reduction in our workforce as well as other steps to streamline our operations, including exiting our distributed products business and significantly decreasing our global footprint outside of the United States to less than a dozen countries or territories. Management currently expects that the strategic realignment will be completed in 2023 and estimates that the total costs incurred may be up to \$170 million for associated employee severance and benefits, losses on asset disposals, and other restructuring costs including the write-off of prepaid assets related to the exit of certain product offerings, professional service fees and contract exit costs. Actual costs may be higher than we expect. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our realignment efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. For example, our divestiture activities may divert management's attention from our core business operations, result in significant write-offs and other charges, and have an adverse effect on existing relationships with partners, customers, patients and third-party payers. We have also terminated early, changed the scope of, or may not be able to perform under certain contracts as a result of our realignment efforts, and we could incur significant liability if we do not successfully negotiate wind-down provisions or new terms. For example, we have informed certain contractual counterparties that we will not be able to perform under our companion diagnostic development agreements. Any of these or other events could adversely affect our financial condition and results of operations. In addition, we may not be able to retain qualified personnel, which may negatively affect our infrastructure and operations or result in a loss of employees and reduced productivity among remaining employees. For example, our turnaround times in returning test results increased recently. Further, the realignment may yield unintended consequences, such as attrition beyond our intended workforce reduction, reduced employee morale, loss of customers or partners, and other adverse effects on our business.

If our management is unable to successfully manage this transition and realignment activities, our expenses may be more than expected and may vary significant from period to period and we may be unable to implement our business strategy. As a result, our future financial performance, operations, and prospects would be negatively affected.

We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.

Our performance, including our research and development programs and laboratory operations, largely depend on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization, including software developers, geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel to process and interpret our genetic tests. In addition, we may need to continue to expand our sales force with qualified and experienced personnel. In July 2022, we initiated a strategic realignment of our operations and began implementing cost reduction programs that will ultimately reduce our workforce by approximately 1,000 employees. This reduction in workforce has and will continue to result in the loss of institutional knowledge and expertise and the reallocation of and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Further, the realignment has and may continue to yield unintended consequences, such as attrition beyond our intended workforce reduction and reduced employee morale. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. If the value of our common stock declines significantly, and remains depressed, as it has in the recent past, or if we do not have enough shares authorized to grant equity awards to new and existing employees, we may not be able to recruit and retain qualified employees. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to scale our business and support our research and development efforts and our clinical laboratory. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows and evolves, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

We need to scale our infrastructure in advance of demand for our tests and other services, and our failure to generate sufficient demand for our tests and other services would have a negative impact on our business and our ability to attain profitability.

Our success depends in large part on our ability to extend our market position, to develop new services, to provide customers with high-quality test reports quickly and at a lower price than our competitors, and to achieve sufficient test volume to realize economies of scale. In order to execute our business model, we intend to continue to invest heavily in order to significantly scale our infrastructure, including our testing capacity and information systems, expand our commercial operations, customer service, billing and systems processes and enhance our internal quality assurance program. We expect that much of this infrastructure growth will be in advance of demand for our tests and other services. Many of our current and future expense levels are fixed. Because the timing and amount of revenue from our services is difficult to forecast, when revenue does not meet our expectations, we may not be able to adjust our spending promptly or reduce our spending to levels commensurate with our revenue. Even if we are able to successfully scale our infrastructure and operations, we cannot assure you that demand for our services will increase at levels consistent with the growth of our infrastructure. If we fail to generate demand commensurate with this growth or if we fail to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition and results of operations could be adversely affected.

The global macroeconomic environment could negatively impact our business, our financial position and our results of operations.

Adverse macroeconomic developments, including inflation, slowing growth, rising interest rates, or recession, may adversely affect our business and financial condition. These developments have caused, and could in the future cause, disruptions and volatility in global financial markets and increased rates of default and bankruptcy, and negatively affect business and consumer spending. Adverse economic conditions have and may continue to increase the costs of operating our business, including vendor, supplier and workforce expenses, and may limit our access to capital or may significantly increase our cost of capital. Management continues to evaluate the impact of macroeconomic events, including inflation, on our business and our future plans and intends to take appropriate measures to help alleviate their impact, but there can be no assurance that these efforts will be successful. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. A severe or prolonged economic downturn, such as the global financial crisis, could also reduce our ability to raise additional capital when needed on acceptable terms, if at all. Presently, we have customers who have been adversely affected by Russia's invasion of Ukraine, and we have experienced some disruption in our engineering productivity as we have sought to assist contractors in both Ukraine and Russia who have been dislocated or who have chosen to flee Russia. Likewise, the capital and credit markets have been and may continue to be adversely affected by the invasion, the possibility of a wider European or global conflict, and global sanctions imposed in response to the invasion. We cannot predict the future trajectory of these risks, including how the macroeconomic environment will evolve or how it will continue to impact us.

Specifically, difficult macroeconomic conditions, such as cost inflation, decreases in per capita income and level of disposable income, increased and prolonged unemployment or a decline in consumer confidence as a result of COVID-19 or otherwise, as well as limited or significantly reduced points of access of our tests, could have a material adverse effect on the demand for our tests. Under difficult economic conditions, consumers may seek to reduce discretionary spending by forgoing our tests. Decreased demand for our tests, particularly in the United States, has negatively affected and could continue to negatively affect our overall financial performance.

We face risks related to health epidemics, including the ongoing COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

Our business has been and could continue to be adversely affected by a widespread outbreak of contagious disease, including the COVID-19 pandemic. Global health concerns relating to COVID-19 have negatively affected the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. As discussed in our prior and current Form 10-K and 10-Q filings, our operations have been and will continue to be impacted by the COVID-19 pandemic and its related economic challenges. Even after COVID-19 has subsided, we may continue to experience an adverse impact to our business as a result of its global economic impact, including any recession that has occurred or may occur in the future.

There are no comparable recent events which may provide guidance as to the effect of the spread of COVID-19, and, as a result, the ultimate impact of COVID-19 or a similar health epidemic is highly uncertain and subject to change.

If third-party payers, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.

Our ability to increase the number of billable tests and our revenue will depend on our success achieving reimbursement for our tests from third-party payers. Reimbursement by a payer may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary, and cost-effective, and/or whether the patient has received prior authorization.

Since each payer makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payer to cover and the amount it will reimburse for our tests will likely be made on an indication-by-indication basis. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our germline tests from most of the large commercial third-party payers in the United States, and the Centers for Medicare & Medicaid Services, or CMS, provides reimbursement for our multi-gene tests for hereditary breast and ovarian cancer-related disorders as well as colon cancer. We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from third-party payers may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive and may not result in payment. In cases where there is not a contracted rate for reimbursement, there is typically a greater coinsurance or copayment requirement from the patient, which may result in further delay or decreased likelihood of collection.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payer to payer, and we have needed additional time and resources to comply with them. We have also experienced, and may continue to experience, delays in or denials of coverage if we do not adequately comply with these requirements. Our third-party payers have also requested, and in the future may request, audits of the amounts paid to us. We have been required to repay certain amounts to payers as a result of such audits, and we could be adversely affected if we are required to repay other payers for alleged overpayments due to lack of compliance with their reimbursement policies. In addition, we have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests and any future tests we may develop or acquire. If we fail to expand and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the markets in which we operate. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.

With the development of next generation sequencing, the clinical genetics market is becoming increasingly competitive, and we expect this competition to intensify in the future. We face competition from a variety of sources, including:

- dozens of relatively specialized competitors focused on genetics applied to healthcare, such as Ambry Genetics, a subsidiary of Realm IDx; Athena Diagnostics and Blueprint Genetics, subsidiaries of Quest Diagnostics; Baylor-Miraca Genetics Laboratories; Caris Life Sciences; Centogene AG; Color Health; Connective Tissue Gene Test, a subsidiary of Health Network Laboratories; Cooper Surgical; Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Exact Sciences; Foundation Medicine, a subsidiary of Roche Holding AG; Fulgent Genetics; GeneDx Holdings; Guardant Health; Integrated Genetics, Sequenom, Correlagen Diagnostics, and MNG Laboratories, subsidiaries of Labcorp; Myriad Genetics; Natera; NeoGenomics; Perkin Elmer; and Tempus Labs; as well as other commercial and academic laboratories;
- a few large, established general testing companies with large market share and significant channel power, such as Labcorp and Quest Diagnostics;
- a large number of clinical laboratories in an academic or healthcare provider setting that perform clinical genetic testing on behalf of their affiliated institutions and often sell and market more broadly; and
- a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness including Illumina, which is also one of our suppliers.

Hospitals, academic medical centers and eventually physician practice groups and individual clinicians may also seek to perform at their own facilities the type of genetic testing we would otherwise perform for them. In this regard, continued development of equipment, reagents, and other materials as well as databases and interpretation services may enable broader direct participation in genetic testing and analysis.

Participants in closely related markets such as clinical trial or companion diagnostic testing could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide such potential competitors with significant advantages.

In addition, the biotechnology and genetic testing fields are intensely competitive both in terms of service and price, and continue to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

We also face competition as a result of our 2021 acquisition of Ciitizen Corporation ("Ciitizen"). Ciitizen competes with companies in the patient data platform business, including, among others, PicnicHealth, All Stripes Research Inc., Seqster PDM, Inc., Apple Inc. ("Apple"), and Flatiron Health, Inc.

We believe the principal competitive factors in our market are:

- breadth and depth of content;
- quality;
- reliability;
- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;
- convenience of testing;
- brand recognition of test provider;
- additional value-added services and informatics tools;
- client service; and
- quality of website content.

Many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, higher margins on their tests, substantially greater financial, technological and research and development resources, selling and marketing capabilities, lobbying efforts, and more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do, sell their tests at prices designed to win significant levels of market share, or obtain reimbursement from more third-party payers and at higher prices than we do. We may not be able to compete effectively against these organizations. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payers are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies as use of next generation sequencing for clinical diagnosis and preventative care increases. Certain of our competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to website and systems development than we can. In the past, our competitors have been successful in recruiting our employees and may continue to recruit qualified employees from us. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. Some of our competitors have obtained approval or clearance for certain of their tests from the FDA. If payers decide to reimburse only for tests that are FDA-approved or FDA-cleared, or if they are more likely to reimburse for such tests, we may not be able to compete effectively unless we obtain similar approval or clearance for our tests. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

The market for patient data software is competitive, and our business will be adversely affected if we are unable to successfully compete.

The market for patient data software is competitive. Other than product innovation and access to healthcare data, there are no substantial barriers to entry in this market, and established or new entities may enter this market in the future. While software internally developed by enterprises represents indirect competition, we also compete directly with packaged application software vendors. In addition, we face actual or potential competition from larger companies such as Apple, and similar companies that may attempt to sell customer engagement software to their installed base.

We believe competition will continue to be substantial as current competitors increase the sophistication of their offerings and as new participants enter the market. Many of our current and potential competitors have longer operating histories, larger customer bases, broader brand recognition, and significantly greater financial, marketing and other resources. With more established and better-financed competitors, these companies may be able to undertake more extensive marketing campaigns, adopt more aggressive pricing policies, and make more attractive offers to businesses to induce them to use their products or services. If we are unable to compete successfully, our business will be adversely affected.

Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including protected health information, or PHI, personally identifiable information, genetic information, credit card information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive patient data through our various customer tools and platforms. In addition to storing and transmitting sensitive data that is subject to multiple legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, viruses, security attacks, ransomware fraud, spikes in customer usage and denial of service issues. There continues to be a significant level of in ransomware and cyber security attacks related to the ongoing conflict between Russia and Ukraine, which could result in substantial harm to internal systems necessary for running our critical operations and revenue generating services.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take what we believe to be reasonable and appropriate measures, including a formal, dedicated enterprise security program, to protect sensitive information from various compromises (including unauthorized access, disclosure, or modification or lack of availability), our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. For example, we have been subject to phishing incidents in the past, and we may experience additional incidents in the future. Any such breach or interruption could compromise our networks, and the information stored therein could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

In addition to data security risks, we face privacy risks. Should we actually violate, or be perceived to have violated, any privacy commitments we make to patients or consumers, we could be subject to a complaint from an affected individual or interested privacy regulator, such as the FTC, a state Attorney General, an EU Member State Data Protection Authority, or a data protection authority in another international jurisdiction. This risk is heightened given the sensitivity of the data we collect.

Any security compromise that causes an apparent privacy violation could also result in legal claims or proceedings and liability and penalties under federal, state, foreign, or multinational laws that regulate the privacy, security, or breach of personal information, such as but not limited to HIPAA, HITECH, the FTC Act, state UDAP data security and data breach notification laws, the GDPR and the UK Data Protection Act of 2018.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. The GDPR took effect in May 2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. Among other requirements, the GDPR imposes strict rules on controllers and processors of personal data, including enhanced protections for “special categories” of personal data, which includes sensitive information such as health and genetic information of data subjects. Maximum penalties for violations of the GDPR are capped at 20.0 million euros or 4% of an organization’s annual global revenue, whichever is greater.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, in June 2018, California adopted the California Consumer Privacy Act of 2018, or the CCPA. The CCPA, is a comprehensive consumer privacy law that took effect in January 2020 and was further amended as of January 1, 2023. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of natural persons who reside in California. The CCPA does not apply to personal information that is PHI under HIPAA. The CCPA also does not apply to a HIPAA-regulated entity to the extent that the entity maintains patient information in the same manner as PHI. In addition, de-identified data as defined under HIPAA is also exempt from the CCPA. Accordingly, we do not have CCPA compliance obligations with respect to most genetic testing and patient information we collect and process. However, we are required to comply with the CCPA insofar as we collect other categories of California consumers’ personal information.

Virginia, Connecticut, Colorado, and Utah have recently enacted similar privacy acts, and dozens of other states in the United States are currently considering similar consumer data privacy laws, which could impact our operations if enacted. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business, results of operations, and financial condition.

It is possible the GDPR, CCPA and other emerging United States and international data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy laws and regulations may differ from country to country and state to state, and our obligations under these laws and regulations vary based on the nature of our activities in the particular jurisdiction, such as whether we collect samples from individuals in the local jurisdiction, perform testing in the local jurisdiction, or process personal information regarding employees or other individuals in the local jurisdiction. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We can provide no assurance that we are or will remain in compliance with diverse privacy and data security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and data security requirements could result in a variety of consequences, including civil or criminal penalties, litigation, or damage to our reputation, any of which could have a material adverse effect on our business.

If we are not able to continue to generate substantial demand for our tests, our commercial success will be negatively affected.

Our business model assumes that we will be able to generate significant test volume, and we may not succeed in continuing to drive adoption of our tests to achieve sufficient volumes. Inasmuch as detailed genetic data from broad-based testing panels such as our tests have only recently become available at relatively affordable prices, the continued pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes. Given the substantial amount of additional information available from a broad-based testing panel such as ours, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate further demand for our tests, we will need to continue to make clinicians aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. A lack of or delay in clinical acceptance of broad-

based panels such as our tests would negatively impact sales and market acceptance of our tests and limit our revenue growth and potential profitability. Genetic testing can be expensive and many potential customers may be sensitive to pricing. In addition, potential customers may not adopt our tests if adequate reimbursement is not available, or if we are not able to maintain low prices relative to our competitors. Also, we may not be successful in increasing demand for our tests through our direct channel, in which we facilitate the ordering of our genetic tests by consumers through an online network of physicians.

If we are not able to generate demand for our tests at sufficient volume, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition and results of operations could be materially harmed.

We have devoted a portion of our resources to research and development activities related to our Personalized Cancer Monitoring ("PCM") service for cancer monitoring. The demand for this service is unproven, and we may not be successful in achieving market awareness and demand for these services through our sales and marketing operations.

Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.

Our success depends on our ability to provide reliable, high-quality tests that incorporate rapidly evolving information about the role of genes and gene variants in disease and clinically relevant outcomes associated with those variants. Errors, such as failure to detect genomic variants with high accuracy, or mistakes, such as failure to identify, or incompletely or incorrectly identifying, gene variants or their significance, could have a significant adverse impact on our business.

Hundreds of genes can be implicated in some disorders, and overlapping networks of genes and symptoms can be implicated in multiple conditions. As a result, a substantial amount of judgment is required in order to interpret testing results for an individual patient and to develop an appropriate patient report. We classify variants in accordance with published guidelines as benign, likely benign, variants of uncertain significance, likely pathogenic or pathogenic, and these guidelines are subject to change. In addition, it is our practice to offer support to clinicians and geneticists ordering our tests regarding which genes or panels to order as well as interpretation of genetic variants. We also rely on clinicians to interpret what we report and to incorporate specific information about an individual patient into the physician's treatment decision.

The marketing, sale and use of our genetic tests could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on, information we provide to clinicians, geneticists or patients, and lead to claims against us if someone were to allege that a test failed to perform as it was designed, if we failed to correctly interpret the test results, if we failed to update the test results due to a reclassification of the variants according to new published guidelines, or if the ordering physician were to misinterpret test results or improperly rely on them when making a clinical decision. In addition, our entry into the reproductive health and pharmacogenetic testing markets expose us to increased liability. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain liability insurance, including for errors and omissions, we cannot assure you that such insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests. The occurrence of any of these events could have an adverse effect on our reputation and results of operations.

Our industry is subject to rapidly changing technology and new and increasing amounts of scientific data related to genes and genetic variants and their role in disease. Our failure to develop tests to keep pace with these changes could make us obsolete.

In recent years, there have been numerous advances in methods used to analyze very large amounts of genomic information and the role of genetics and gene variants in disease and treatment therapies. Our industry has and will continue to be characterized by rapid technological change, increasingly larger amounts of data, frequent new testing service introductions and evolving industry standards, all of which could make our tests obsolete. Our future success will also depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. Our tests could become obsolete and our business adversely affected unless we continually update our

offerings to reflect new scientific knowledge about genes and genetic variations and their role in diseases and treatment therapies.

Our success will depend in part on our ability to generate sales using our internal sales team and through alternative marketing strategies.

We may not be able to market or sell our current tests and any future tests we may develop or acquire effectively enough to drive demand sufficient to support our planned growth. We currently sell our tests primarily through our internal sales force. Historically, our sales efforts have been focused primarily on hereditary cancer and more recently on reproductive health. Our efforts to sell our tests to clinicians and patients outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. In addition to the efforts of our sales force, future sales will depend in large part on our ability to develop and substantially expand awareness of our company and our tests through alternative strategies including through education of key opinion leaders, through social media-related and online outreach, education and marketing efforts, and through focused channel partner strategies designed to drive demand for our tests. We also may continue to spend on consumer advertising in connection with our direct channel to consumers, which could be costly. We have limited experience implementing these types of marketing efforts. We may not be able to drive sufficient levels of revenue using these sales and marketing methods and strategies necessary to support our planned growth, and our failure to do so could limit our revenue and potential profitability.

We also use a limited number of distributors to assist internationally with sales, logistics, education and customer support. Sales practices utilized by our distributors that are locally acceptable may not comply with sales practices standards required under U.S. laws that apply to us, which could create additional compliance risk. If our sales and marketing efforts are not successful outside the United States, we may not achieve significant market acceptance for our tests outside the United States, which could adversely impact our business.

Impairment in the value of our goodwill or other intangible assets has and may in the future have a material adverse effect on our operating results and financial condition.

We record goodwill and intangible assets at fair value upon the acquisition of a business. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired. Goodwill and indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of our reporting unit has and may in the future result in an impairment of goodwill or intangible assets and, in turn, a charge to net income. These charges in the three months ended June 30, 2022 and any future charges related to intangible assets have, and may in the future have, a material adverse effect on our results of operations or financial condition.

During the three months ended June 30, 2022, as a result of a significant, sustained decline in our stock price and related market capitalization and lower than expected financial performance, we performed an impairment assessment of goodwill, in-process research and development ("IPR&D") intangible assets, and long-lived assets, including definite-lived intangibles.

For our goodwill, we measured the fair value of the reporting unit utilizing the discounted cash flow method under the income approach. This approach relies on significant unobservable inputs including, but not limited to, management's forecasts of projected revenue associated with future cash flows, discount rates, and control premium. Based on this analysis, we recognized a non-cash, pre-tax goodwill impairment charge of \$2.3 billion during the three months ended June 30, 2022, which is included in goodwill and IPR&D impairment expense in the consolidated statements of operations.

We also identified indicators of impairment related to the IPR&D intangible asset initially recognized as part of the acquisition of Singular Bio, Inc. ("Singular Bio") that it was more likely than not that the asset is impaired. We identified conditions during the three months ended June 30, 2022 such as alternative technologies and uncertainties around the desired outcome of our in-development asset and other economic factors that raised issues with the realizability of our asset. As a result of our evaluation, we recognized a non-cash, pre-tax impairment charge of \$30.0 million during the three months ended June 30, 2022 related to the IPR&D intangible asset, which is included in goodwill and IPR&D impairment expense in the consolidated statements of operations.

We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments, materials and services, and we may not be able to find replacements or immediately transition to alternative suppliers.

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Illumina, IDT, QIAGEN, Roche Holdings Ltd. and Twist Bioscience Corporation for certain laboratory substances used in the chemical reactions incorporated into our processes, which we refer to as reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We do not have short- or long-term agreements with most of our suppliers, and our suppliers could cease supplying these materials and equipment at any time, or fail to provide us with sufficient quantities of materials or materials that meet our specifications. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations could impact our supply chain and laboratory operations as well as our ability to conduct our tests, and it could take a substantial amount of time to integrate replacement equipment into our laboratory operations.

We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot assure you that we will be able to secure alternative equipment, reagents and other materials, and bring such equipment, reagents and materials online and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, we cannot assure you that replacement sequencers and associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business, financial condition, results of operations and reputation could be adversely affected.

We depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process and drug metabolism, our patient data platform, our clinical report optimization systems, our customer-facing web-based software, our customer reporting, and our various customer tools and platforms. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, customer relationship management, regulatory compliance and other infrastructure operations. In addition, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design, and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, and general administrative activities, including financial reporting.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to clinicians, billing payers, processing reimbursement appeals, handling physician or patient inquiries, conducting research and development activities, and managing the administrative and financial aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and results of operations.

Technical problems have arisen, and may arise in the future, in connection with our data and systems, including those that are hosted by third-party providers, which have in the past and may in the future result in interruptions in our business and operations. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

If our laboratories or other facilities become inoperable due to disasters, health epidemics or for any other reasons, we will be unable to perform our tests and our business will be harmed.

We perform all of our tests at our production facilities in San Francisco, California, in Iselin, New Jersey, and in Seattle, Washington. We also plan to open a new laboratory and production facility in Morrisville, North Carolina. Our laboratories and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use. Our laboratories may be harmed or rendered inoperable or inaccessible due to natural or man-made disasters, including earthquakes, hurricanes, flooding, fire and power outages, or by health epidemics, such as the COVID-19 pandemic, which may render it difficult or impossible for us to perform our tests for some period of time. This risk of natural disaster is especially high for us since we perform the majority of our tests at our San Francisco laboratory, which is located in an active seismic region, and we do not have a redundant facility to perform the same tests in the event our San Francisco laboratory is inoperable. The inability to perform our tests or the backlog that could develop if our laboratories are inoperable for even a short period of time may result in the loss of customers or harm our reputation. If a natural disaster were to damage one of our facilities significantly or if other events were to cause our operations to fail or be significantly curtailed, we may be unable to provide our services, or develop new services. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all. The inability to open the planned facility in North Carolina, delays in opening such facility or failure to obtain required permits, licenses, or certifications, could result in increased costs and prevent us from realizing the intended benefits of the new facility.

The recent changes in our leadership may adversely affect our business.

In July 2022, in connection with our strategic realignment, we announced the appointment of Kenneth D. Knight, who had served as our Chief Operating Officer since 2020, as our Chief Executive Officer. We also announced that Dr. Sean E. George, who co-founded our company and served as our Chief Executive Officer since 2017, would support our company through a transition period as a consultant. These changes in our executive management, and any future changes, as well as the effects of our business realignment, could disrupt our business, and could impact our ability to preserve our culture, which could negatively affect our ability to recruit and retain personnel. If we are not successful in managing the transition of Mr. Knight into his new role, it could be viewed negatively by our customers, employees or investors and could have an adverse impact on our business. Further, these changes also increase our dependency on other members of our executive management team. If we lose the services of any member of the executive management team or any key personnel, we may not be able to secure a suitable or qualified replacement, which could disrupt our business and could be particularly disruptive considering our strategic realignment.

Development of new tests is a complex process, and we may be unable to commercialize new tests on a timely basis, or at all.

We cannot assure you that we will be able to develop and commercialize new tests on a timely basis. Before we can commercialize any new tests, we will need to expend significant funds in order to:

- conduct research and development;
- further develop and scale our laboratory processes; and
- further develop and scale our infrastructure to be able to analyze increasingly larger and more diverse amounts of data.

Our testing service development process involves risk, and development efforts may fail for many reasons, including:

- failure of any test to perform as expected;
- lack of validation or reference data; or
- failure to demonstrate utility of a test.

As we develop tests, we will have to make significant investments in development, marketing and selling resources. In addition, competitors may develop and commercialize competing tests faster than we are able to do so.

Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests.

Genetic testing has raised ethical, legal and social issues regarding privacy rights and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genomic tests even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests, either of which could have an adverse effect on our business, financial condition or results of operations.

We have acquired and may continue to acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.

As part of our business strategy, we have pursued and expect to continue to evaluate acquisitions of complementary businesses or assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. Since 2017, we have acquired numerous companies.

With respect to our acquired businesses and any acquisitions we may make in the future, we may not be able to integrate these businesses successfully into our existing business, and we could assume unknown or contingent liabilities. Acquisitions by us have, and may in the future, result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Furthermore, as we experienced in the past, the loss of customers, payers, partners, suppliers or key management following the completion of any acquisitions by us could harm our business. In addition, as part of our strategic realignment, we have and may continue to divest assets acquired in previous acquisitions at substantial discounts to the price we paid, or without realizing the benefits we intended at the time of the acquisition. Changes in services, sources of revenue, and branding or rebranding initiatives may involve substantial costs and may not be favorably received by customers, resulting in an adverse impact on our financial results, financial condition and stock price. Integration of an acquired company or business also may require management's time and resources that otherwise would be available for ongoing development of our existing business. We may also need to divert cash from other uses to fund these integration activities and these new businesses. Ultimately, we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment, or these benefits may take longer to realize than we expected.

In connection with certain of our completed acquisitions, we have agreed to pay cash and/or stock consideration that is contingent upon the achievement of specified objectives, such as development objectives, regulatory submissions, regulatory approvals and revenue related to certain products. As of the date of the applicable acquisition, we record a contingent liability representing the estimated fair value of the contingent consideration we expect to pay. On a quarterly basis, we reassess these obligations and, in the event our estimate of the fair value of the contingent consideration changes, we record increases or decreases in the fair value as an adjustment to operating expense, which could have a material impact on our results of operations. In addition, in connection with our strategic realignment, we have recently divested or sublicensed certain product offerings, technologies and assets that we had acquired in prior years.

To finance any acquisitions or investments, we may raise additional funds, which could adversely affect our existing stockholders and our business. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. In addition, our stockholders may experience substantial dilution as a result of additional securities we may issue for acquisitions. Open market sales of substantial amounts of our common stock issued to stockholders of companies we acquire could also depress our stock price. Additional funds may not be available on terms that are favorable to us, or at all.

Our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- logistics and regulations associated with shipping samples, including infrastructure conditions, customs and transportation delays;
- limits on our ability to penetrate international markets if we do not to conduct our tests locally;
- natural disasters and outbreaks of disease, including the ongoing COVID-19 pandemic;
- political and economic instability, including wars such as the current conflict in Ukraine, terrorism and political unrest, boycotts, curtailment of trade, government sanctions and other business restrictions;
- inflationary pressures, such as those the global market is currently experiencing, which have and may increase costs for materials, supplies, and services; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our international operations and, consequently, our revenue and results of operations.

In addition, applicable export or import laws and regulations such as prohibitions on the export of samples imposed by countries outside of the United States, or international privacy or data restrictions that are different or more stringent than those of the United States, may require that we build additional laboratories or engage in joint ventures or other business partnerships in order to offer our tests internationally in the future. Any such restrictions would impair our ability to offer our tests in such countries and could have an adverse effect on our business, financial condition and results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

At December 31, 2022, we have substantial deferred tax assets consisting of federal and state net operating losses and tax credit carryforwards. At December 31, 2022, our total gross deferred tax assets were \$795.5 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, our net deferred tax assets have been fully offset by a valuation allowance. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% stockholders" that exceeds 50 percentage points over a rolling three-year period. Some of our prior acquisitions have resulted in an ownership change, and we may experience ownership changes in the future. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, or other future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. In addition, the Tax Cuts and Jobs Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Also, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks related to our indebtedness

We have a large amount of debt, servicing our debt requires a significant amount of cash, we may not have sufficient cash flow from our business to service our debt, and we may need to refinance all or a significant portion of our debt.

In September 2019, we issued \$350.0 million aggregate principal amount of our convertible senior notes due 2024 in a private placement, and in April 2021 we issued \$1,150.0 million aggregate principal amount of our convertible senior notes due 2028 in a private placement.

Our substantial leverage could have significant negative consequences for our future operations, including:

- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financial for working capital, acquisitions, research and development expenditures, and general corporate purposes;
- requiring the dedication of a substantial portion of our cash flow or our existing cash to service our indebtedness, thereby reducing the amount of our cash available for other purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; or
- placing us at a possible competitive disadvantage compared to less leveraged competitors and competitors that have better access to capital resources.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt, including paying off the principal when due, and make necessary capital expenditures. The conversion prices of our convertible notes are significantly higher than the prevailing market prices for our common stock, and our stock price would have to increase significantly in order for holdings to convert our notes prior to maturity. If we are unable to generate cash flow necessary to service or repay our debt at maturity, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time, and the terms of any such refinancing may be less favorable to us than the terms of our current indebtedness. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to settle conversions of our convertible senior notes in cash or to repurchase the notes upon a fundamental change, and our current credit agreement contains and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the notes.

Holders of our convertible senior notes have the right to require us to repurchase all or any portion of their notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. The repurchase price for our convertible senior notes due 2028 will also include unpaid interest on those notes to the maturity date. In addition, upon conversion of the notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the notes being converted. However, we only have limited ability to make those cash payments under our credit agreement and, even if the credit agreement limitations are no longer in effect, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of notes surrendered therefor or notes being converted. In addition, our ability to repurchase the notes or to pay cash upon conversions of the notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the indentures governing the notes or to pay any cash payable on future conversions of the notes as required by the indentures would constitute a default under the relevant indenture. A default under an indenture or the occurrence of the fundamental change itself could also lead to a default under our credit agreement and any agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and to repay or repurchase our convertible senior notes.

The conditional conversion feature of our convertible senior notes due 2024, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of our convertible senior notes due 2024 is triggered, holders of such notes will be entitled to convert the notes at any time during specified periods at their option. If one or more holders elect to convert their notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

Risks related to government regulation

If the FDA regulates the tests we currently offer as LDTs as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.

We provide many of our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by CLIA, and state law, respectively).

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality system regulations, premarket clearance or premarket approval, and post-market controls). See Part I, Item 1. under the heading "Regulation—Federal oversight of laboratory developed tests" for a description of applicable federal regulations, which is incorporated by reference herein.

If the FDA ultimately regulates certain LDTs, whether via individualized enforcement action, more generally as outlined in final guidance or final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition and results of operations.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

If we fail to comply with federal, state and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of health of, human beings. CLIA regulations establish specific requirements and standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers, for our tests.

We are also required to maintain certain in-state and out-of-state laboratory licenses and approvals to conduct testing. For more information about our federal (CLIA) and state laboratory licenses and approvals, please see Part I, Item 1. under the headings "Regulation—Clinical Laboratory Improvement Amendments of 1988, or CLIA" and "Regulation—State laboratory licensure requirements," which are incorporated by reference herein. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of samples necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays.

In order to eventually market certain of our current or future products and services in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-

jurisdiction basis regarding quality, safety, performance and efficacy. In addition, clinical trials or clinical investigations conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory clearance, authorization or approval in one country does not guarantee regulatory clearance, authorization or approval in any other country. For example, the performance characteristics of certain of our products and services may need to be validated separately in specific ethnic and genetic populations. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory clearance, authorization or approval could result in difficulties and costs for us and our collaborators and require additional preclinical studies, clinical trials or clinical investigations which could be costly and time-consuming. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of certain of our products and services in those countries. The foreign regulatory clearance, authorization or approval process involves all of the risks and uncertainties associated with FDA clearance, authorization or approval. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products and services will be unrealized.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, cancellation of the laboratory's approval to receive Medicare and Medicaid payment for its services, exclusion from some healthcare systems' programs, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certifications, a state or foreign license, or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

The College of American Pathologists, or CAP, maintains a clinical laboratory accreditation program. CAP asserts that its program is "designed to go well beyond regulatory compliance" and helps laboratories achieve the highest standards of excellence to positively impact patient care. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. We have CAP accreditations for our laboratories. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- HIPAA and HITECH, which set forth comprehensive federal standards with respect to the privacy and security of protected health information, breach notification requirements, and requirements for the use of certain standardized electronic transactions;
- the GDPR, which imposes strict privacy and security requirements on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, including sensitive information such as health and genetic information of data subjects;
- the CCPA and other, similar state consumer privacy laws, which, among other things, regulate how subject businesses may collect, use, and disclose the personal information of consumers in the regulated state, afford rights to consumers that they may exercise against businesses that collect their information, and require implementation of reasonable security measures to safeguard personal information of consumers;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or recommend purchasing, leasing or ordering, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;

- The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and reaches beyond federal health care programs, to include private insurance;
- the federal physician self-referral law, known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity unless an exception applies, and prohibits an entity from billing for designated health services furnished pursuant to a prohibited referral;
- the federal false claims law, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the HIPAA fraud and abuse provisions, which create new federal criminal statutes that prohibit, among other things, defrauding health care benefit programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;
- the 21st Century Cures Act information blocking prohibition, which prohibits covered actors from engaging in certain practices that are likely to interfere with the access, exchange, or use of electronic health information;
- the federal Physician Payments Sunshine Act, which requires reporting of certain payments and other transfers of value made by applicable manufacturers, directly or indirectly, to or on behalf of various healthcare professionals (including doctors, physician assistants, and nurse practitioners) and teaching hospitals, and requires reporting of certain ownership and investment interests held by physicians and their immediate family members as well as similar state laws that require reporting of information in addition to what is required under the federal Physician Payments Sunshine Act;
- state laws that limit or prohibit the provision of certain payments and other transfers of value to certain covered healthcare providers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payers; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance may also be subject to governmental review. The growth of our business and our operations outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. In October 2021, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting that we produce certain documents regarding our sponsored testing programs. We have produced documents and information in response to the subpoena and are cooperating fully with the investigation. Although we remain committed to compliance with all applicable laws and regulations, we cannot predict the outcome of this investigation or any other requests or investigations that may arise in the future regarding these or other subject matters. Any action brought against us for violation of the above-referenced or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the

operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in Federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Healthcare policy changes, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition, results of operations and cash flows.

In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Policy changes or implementation of new health care legislation could result in significant changes to health care systems. In the United States, this could include potential modification or repeal of all or parts of the Affordable Care Act.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, as amended, and its implementing regulations, clinical laboratories must report to CMS private payer rates beginning in 2017, and then in 2024 and every three years thereafter for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests and every year for advanced diagnostic laboratory tests.

We do not have "advanced diagnostic laboratory test" status for our tests, but in the event that we obtain designation for one or more of our tests as an advanced diagnostic laboratory test and the tests are determined by CMS to meet these criteria or new criteria developed by CMS, we would be required to report private payer data for those tests annually. Otherwise, we will be required to report private payer rates for our tests on an every three-years basis starting in 2023. Laboratories that fail to timely report the required payment information may be subject to substantial civil money penalties.

See Part I, Item 1. under the heading "Regulation—Reimbursement" for a description of how public and private payers pay for our products and services, which is incorporated by reference herein. Changes in these payments and the methodologies used to determine payment amounts could have a significant impact on our financial condition, results of operations and cash flows.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. For instance, the payment reductions imposed by the Affordable Care Act and the expansion of the federal and state governments' role in the U.S. healthcare industry as well as changes to the reimbursement amounts paid by payers for our tests and future tests or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would increase our billing and collecting costs and decrease our revenue.

If we use hazardous materials in a manner that causes injury, we could be liable for resulting damages.

Our activities currently require the use of hazardous chemicals and biological material. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. In 2018, we decommissioned our laboratory in Massachusetts; however, we could be held liable for any damages resulting from our prior use of hazardous chemicals and biological materials at this facility. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

We could be adversely affected by violations of the FCPA and other worldwide anti-bribery laws.

We are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We use a limited number of independent distributors to sell our tests internationally, which requires a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing

their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

Risks related to our intellectual property

One of our competitors has alleged that our Anchored Multiplex PCR, or AMP, chemistry and products using AMP are infringing on its intellectual property, and we may be required to redesign the technology, obtain a license, cease using the AMP chemistry altogether and/or pay significant damages, among other consequences, any of which would have a material adverse effect on our business as well as our financial condition and results of operations.

Our AMP chemistry is the foundation of our PCM service. One of our competitors, Natera, Inc., or Natera, has filed complaints against ArcherDX, LLC ("ArcherDX"), Invitae and Genosity, Inc. ("Genosity") alleging that our products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe certain patents. A description of this ongoing litigation is provided in Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report.

If any of our products or our use of AMP chemistry is found to infringe any of Natera's patents, we could be required to redesign our technology or obtain a license from Natera to continue developing, manufacturing, marketing, selling and commercializing AMP and related products. However, we may not be successful in the redesign of its technology or able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving Natera and other third parties the right to use the same technologies licensed to us, and Natera could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to permanently cease developing, manufacturing, marketing and commercializing our products that are found to be infringing. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed Natera's asserted patents. Even if we were ultimately to prevail, litigation with Natera could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We cannot reasonably estimate the final outcome, including any potential liability or any range of potential future charges associated with these litigations. However, any finding of infringement by us of Natera's asserted patents could have a material adverse effect on our business, as well as our financial condition and results of operations.

Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation will require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price.

Our commercial success will depend in part on our avoiding infringement of patents and proprietary rights of third parties, including for example the intellectual property rights of competitors. As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests, and enter new markets, competitors might claim that our tests infringe or misappropriate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. Our activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. For example, as discussed in the preceding risk factor, we are currently engaged in litigation with a competitor of ArcherDX alleging infringement. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We may be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, regardless of merit, could cause us to incur substantial expenses and be a substantial diversion of our employee resources. Any adverse ruling or perception of an adverse ruling in defending

ourselves could have a material adverse impact on our business and stock price. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, possibly including treble damages and attorneys' fees if we are found to have willfully infringed patents; (2) obtain one or more licenses, which may not be available on commercially reasonable terms (if at all); (3) pay royalties; and/or (4) redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, all of which could have a material adverse impact on our cash position and business and financial condition.

If licenses to third-party intellectual property rights are or become required for us to engage in our business, we may be unable to obtain them at a reasonable cost, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in the introduction of tests while we attempt to develop alternatives. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing tests, which could materially affect our ability to grow and thus adversely affect our business and financial condition.

Developments in patent law could have a negative impact on our business.

Although we view current U.S. Supreme Court precedent to be aligned with our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts (such as patient genetic data) and an understanding of that fact's implications (such as a patient's risk of disease associated with certain genetic variations) should not be patentable, it is possible that subsequent determinations by the U.S. Supreme Court or other federal courts could limit, alter or potentially overrule current law. Moreover, from time to time the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office, or USPTO, may change the standards of patentability, and any such changes could run contrary to, or otherwise be inconsistent with, our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts and an understanding of that fact's implications should not be patentable, which could result in third parties newly claiming that our business practices infringe patents drawn from categories of patents which we currently view to be invalid as directed to unpatentable subject matter. For example, on August 2, 2022, Senator Thom Tillis (R-NC) introduced a bill entitled The Patent Eligibility Restoration Act of 2022 that would overrule current U.S. Supreme Court precedent concerning the scope of patentable subject matter. If the proposed bill were to be enacted into law, there could be an increase in third-party claims to patent rights over correlations between patient genetic data and its interpretation and such third parties may assert that our business practices infringe some of those resulting patent rights.

Our inability to effectively protect our proprietary technologies, including the confidentiality of our trade secrets, could harm our competitive position.

We currently rely upon trade secret protection and copyright, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, and to a limited extent patent protection, to protect our confidential and proprietary information. Although our competitors have utilized and are expected to continue utilizing similar methods and have aggregated and are expected to continue to aggregate similar databases of genetic testing information, our success will depend upon our ability to develop proprietary methods and databases and to defend any advantages afforded to us by such methods and databases relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our methods and databases and thereby erode any competitive advantages we may have.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. In this regard, we have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, we expect that potential patent coverage we may obtain will not be sufficient to prevent substantial competition. In this regard, we believe it is probable that others will independently develop similar or alternative technologies or design around those technologies for which we may obtain patent protection. In addition, any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. Questions as to inventorship or ownership may also arise. Any finding that our patents or applications are unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, which would be expensive, and, if we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel.

We expect to rely primarily upon trade secrets and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. Among other things, we seek to protect our trade secrets and confidential information by entering into confidentiality agreements with employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees and consultants will provide meaningful protection for our trade secrets and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Accordingly, there also can be no assurance that our trade secrets will not otherwise become known or be independently developed by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

As an example, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system will likely be introduced by the end of 2023, which would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks related to being a public company

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the Securities and Exchange Commission, or SEC, and the New York Stock Exchange, or NYSE, impose a number of requirements on public companies, including with respect to corporate governance practices. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In addition, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, enacted in 2010, includes significant corporate governance and executive-compensation-related provisions. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. If these requirements divert the attention of our management and personnel from other aspects of our business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, these rules and regulations applicable to public companies substantially increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time consuming and costly. It may also be more expensive for us to obtain director and officer liability insurance.

If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

We are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have compiled the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. As we acquire companies, we will need to establish adequate controls and integrate them into our internal control system. We need to maintain and enhance these processes and controls as we grow and we have required, and may continue to require, additional personnel and resources to do so.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal controls, our management will be unable to conclude that our internal control over financial reporting is effective. Our independent registered public accounting firm is required to issue an attestation report on the effectiveness of our internal control over financial reporting every fiscal year. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in the restatement of our financial results in the future.

General risk factors

Our stock price is volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

The trading price of our common stock is volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated fluctuations in our operating results;
- effects of our strategic realignment and workforce reduction and our ability to achieve the intended benefits of these activities;
- costs associated with our strategic realignment;

- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our stock;
- our substantial leverage and market perceptions regarding the same;
- the level of short interest in our stock, and the effect of short sellers on the price of our stock;
- actual or anticipated changes in regulatory oversight of our business;
- additions or departures of key management or other personnel;
- disputes or other developments related to our intellectual property or other proprietary rights, including litigation;
- changes in reimbursement by current or potential payers;
- general economic and market conditions; and
- issuances of significant amounts of our common stock.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. The closing price of our common stock on the NYSE ranged from \$2.36 to \$11.65 between February 1, 2022 through January 31, 2023. Broad market and industry factors, including the COVID-19 pandemic, as well as general economic, political and geopolitical, and market conditions such as recessions, wars such as the current conflict in Ukraine, elections, interest rate changes, or cost inflation, may seriously affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock, change their price targets, issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, the terms of our credit agreement restrict our ability to pay dividends. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 20,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our chair of the board or our chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum; and
- require a super-majority of votes to amend certain of the above-mentioned provisions as well as to amend our bylaws generally.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law; or
- any action asserting a claim against us governed by the internal affairs doctrine.

Section 27 of the Securities Exchange Act of 1934, or Exchange Act, creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 22 of the Securities Act of 1933, or Securities Act, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or

proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of December 31, 2022, we had outstanding 245.6 million shares of our common stock, options to purchase 2.4 million shares of our common stock (of which 1.4 million were exercisable as of that date) and outstanding restricted stock units, or RSUs, representing 11.9 million shares of our common stock (which includes an estimated number of RSUs, subject to certain employees' continued service with us, or time-based RSUs, and RSUs that are performance based RSUs, or PRSUs, granted in connection with an acquisition). The foregoing does not include 8.8 million shares of common stock that may be issuable in connection with indemnification hold-backs and contingent consideration related to our acquisitions, shares that may be issuable in the future in connection with the convertible senior notes, or shares issuable pursuant to our May 2021 sales agreement with Cowen and Company, LLC under which we may offer and sell from time to time at our sole discretion shares of our common stock in an aggregate amount not to exceed \$400 million. In addition, as of December 31, 2022, 5.5 million and 2.1 million shares of common stock are available for future issuance under our 2015 Stock Incentive Plan and Employee Stock Purchase Plan, respectively, and as of January 1, 2023, 9.8 million and 2.5 million additional shares of common stock became available for future issuance under our 2015 Stock Incentive Plan and our Employee Stock Purchase Plan, respectively. The sale or the availability for sale of a large number of shares of our common stock in the public market could cause the price of our common stock to decline.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Our headquarters and main production facility is located in San Francisco, California, where we currently lease and occupy approximately 103,000 square feet of laboratory and office space. The lease for this facility expires in October 2026 and we may renew the lease for an additional ten years.

Following our strategic realignment, in December 2022, we entered into an agreement to sublease 41,630 square feet of office space located in a multi-tenant building in Boulder, Colorado. This sublease agreement expires on January 31, 2025.

We also lease approximately 573,000 square feet of additional office and laboratory space domestically in California, Colorado, Massachusetts, New Jersey, New York, North Carolina, Texas and Washington, and internationally in Australia, Belgium, Israel and Japan. As part of our strategic realignment announced in July 2022, we began cost reduction initiatives including office and laboratory space consolidation and a reduction in our international footprint. Under this strategic realignment, we decided to cease use of certain leased premises and actively began looking to sublease certain facilities.

We believe that our facilities are adequate to meet the needs for our business in the near term.

ITEM 3. Legal Proceedings

For a discussion of legal matters as of December 31, 2022, see Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report, which is incorporated into this item by reference.

ITEM 4. Mine Safety Disclosure

Not applicable.

PART II

ITEM 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock has been publicly traded on the NYSE under the symbol “NVTA” since February 12, 2015. Prior to that time, there was no public market for our common stock.

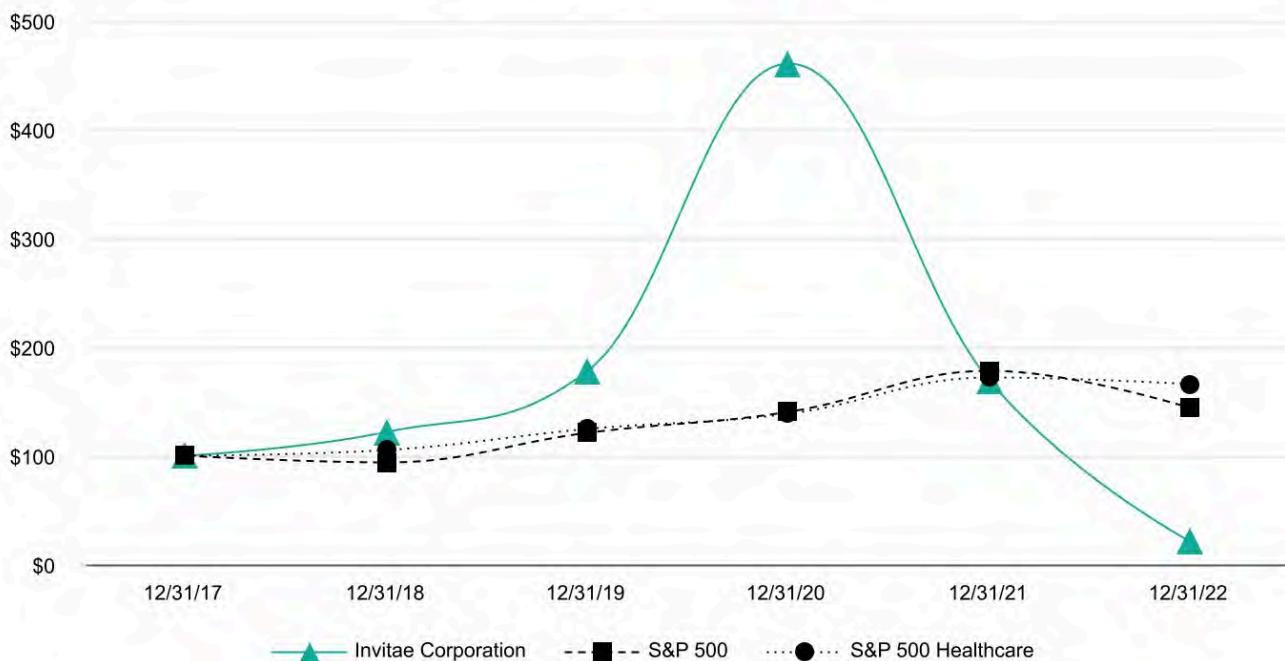
As of February 24, 2023, there were 276 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. In addition, the terms of the credit agreement restrict our ability to pay dividends. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements and general business conditions and other factors that our board of directors may deem relevant.

Stock performance graph

The following information shall not be deemed to be soliciting material or to be filed with the SEC, or subject to Regulations 14A or 14C under the Securities Exchange Act of 1934, or Exchange Act, or to the liabilities of Section 18 of the Exchange Act nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

Comparison of Historical Cumulative Total Return Among Invitae Corporation, the S&P 500 Index and the S&P 500 Healthcare Index (*)



(*) The above graph shows the cumulative total stockholder return of an investment of \$100 in cash on December 31, 2017 through December 31, 2022 for: (i) our common stock; (ii) the S&P 500 Index; and (iii) the S&P 500 Healthcare Index. All values assume reinvestment of the full amount of all dividends. The comparisons in the table are not intended to be forecasts or indicative of future stockholder returns.

	<u>12/31/2017</u>	<u>12/31/2018</u>	<u>12/31/2019</u>	<u>12/31/2020</u>	<u>12/31/2021</u>	<u>12/31/2022</u>
Invitae Corporation	\$ 100.00	\$ 121.81	\$ 177.64	\$ 460.46	\$ 168.17	\$ 20.48
S&P 500	\$ 100.00	\$ 93.76	\$ 120.84	\$ 140.49	\$ 178.27	\$ 143.61
S&P 500 Healthcare Index	\$ 100.00	\$ 104.69	\$ 124.25	\$ 138.45	\$ 171.90	\$ 165.80

ITEM 6. [Reserved]

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Historic results are not necessarily indicative of future results.

Business overview

We are focused on making comprehensive and high-quality, medical genetic testing information more accessible and instrumental to the healthcare ecosystem and stakeholders, including patients, healthcare providers, payers, biopharma partners, patient advocacy groups, and more. We offer genetic testing across multiple clinical areas, including hereditary cancer, precision oncology, women's health, rare diseases and pharmacogenomics. Medical genetics is central to health outcomes and we are working to bring it to the mainstream by enhancing the customer experience, lowering the costs, removing barriers to adoption, and expanding insights and solutions. Ultimately, we expect the utility of the accumulated data will compound, enabling improved individual and population health and advancing the benefits of molecular medicine around the globe.

Historically, a component of our strategy was to augment internal growth with complementary transactions. We did not complete any acquisitions in fiscal year 2022 but did have dispositions related to our strategic realignment. In 2021, we completed the acquisitions of Reference Genomics, Inc. d/b/a One Codex, or One Codex, Genosity, Medneon LLC, or Medneon, Ciitizen, and Stratify Genomics Inc., or Stratify. See Note 4, "Business combinations and dispositions" and Note 5, "Goodwill and intangible assets" in the Notes to Consolidated Financial statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information on our recent acquisitions and dispositions.

For the years ended December 31, 2022, 2021 and 2020, our revenue was \$516.3 million, \$460.4 million and \$279.6 million, respectively, and we incurred net losses of \$3.1 billion, \$379.0 million and \$602.2 million, respectively. At December 31, 2022, our accumulated deficit was \$4.8 billion.

In 2022, 2021 and 2020, we generated 1,290,000, 1,169,000 and 659,000 billable units, respectively. We calculate volume using billable units, which are billable events that include individual test reports released and individual reactions shipped related to our precision oncology products. We refer to the set of reagents needed to perform a next generation sequencing ("NGS") test for our research use only ("RUO") product as a "reaction." As part of the strategic realignment, we discontinued the sale of and sublicensed to others our distributed precision oncology products, which includes our RUO kit and IVD product offerings. For the year ended December 31, 2022, approximately 53% of the billable volume generated were billable to patients and institutional customers (e.g., hospitals, clinics, medical centers, biopharmaceutical partners), and the remainder were billable to government and private insurance payers. Many of the gene tests on our assays are reimbursable by health insurance companies. However, when we do not have reimbursement policies or contracts with private insurers, or at times due to other situations, our claims for reimbursement may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. Even if we are successful in achieving reimbursement, we may be paid at lower rates than if we were under contract with a third-party payer. When there is not a contracted rate for reimbursement, there is typically a greater payment requirement from the patient that may result in further delay in payment for these tests.

We believe that the keys to long-term profitable growth are:

- **Consistently improve the client experience:** efficient ordering; comprehensive choices; reliable turnaround time; easy-to use;
- **Lower costs and higher reimbursement:** align our cost structure with our streamlined product portfolio and implement operational discipline; reduce the costs associated with performing our genetic tests; achieve broad reimbursement coverage for our tests from third-party payers and increase the amount we receive from other types of payers; focus our efforts on testing categories that are more regularly reimbursed to avoid the process of appeals and slow or non-existing payment;
- **Advance insights and solutions:** optimize the amount of genetic content we offer and is used by providers across the range of healthcare platforms; deliver actionable insights through digital health solutions; develop our data services;
- **Improve affordability and accessibility and serve more patients:** provide affordable pricing for genetic analysis and interpretation; partner to reach underserved populations; expand call points;
- **Drive adoption:** increase physician and patient utilization of our platform for ordering and delivery of results; and

- **Attract new partners:** increasing the number of strategic partners working with us to add value for all our customer segments.

Strategic realignment

On July 18, 2022, we initiated a strategic realignment of our operations and began implementing cost reduction programs in order to accelerate our path to positive operating cash flow. We are in the process of realigning and sharpening our focus on the portfolio of businesses that we believe can generate margins and deliver returns to fuel future investment. In the testing business, we have shifted operational and commercial efforts to accelerate positive cash flow by maintaining robust support of the higher-margin, higher-growth testing opportunities among hereditary cancer, precision oncology, women's health, rare disease and pharmacogenomics. We also plan to continue our expansion and integration of key digital health-based technologies and services in order to create a differentiated model in genetic health. Longer-term, we remain committed to our data platform and patient network. We believe that we hold significant growth potential and intend to continue to prioritize the tools, partnerships and applications that support the development of this platform as the catalyst for the future of healthcare.

The strategic realignment included a reduction in workforce of approximately 1,000 positions, lab and office space consolidation, portfolio optimization, decrease in other operating expenses, as well as a reduced international footprint. Management currently expects the strategic realignment will be completed in 2023 and estimates that the total costs incurred may be up to \$170 million for associated employee severance and benefits, asset impairments and losses on asset disposals, and other restructuring costs related to the realignment, which excludes the gain on sale of the RUO kit assets. This reflects the best estimate of management, which may be revised in subsequent periods as the strategic realignment progresses. With the major initiatives in our strategic realignment largely complete as of December 31, 2022, we anticipate annualized cash savings of approximately \$326 million, which is expected to be fully realized by the end of fiscal year 2023. We may not realize, in full or in part, the anticipated annualized cash savings due to unforeseen difficulties or delays in implementing further decreases in other operating expenses.

We expect to continue to incur operating losses for the near term as we execute on the strategic realignment of our operations. If we are unable to achieve these objectives and successfully grow revenue and manage our costs, we may not be able to achieve positive operating cash flow in the near term or at all.

Russia and Ukraine Conflict

During the first quarter of 2022, Russia commenced a military invasion of Ukraine, and the ensuing conflict has created disruption in the region and around the world. We have suspended operations in Russia, which has not and is not expected to have a material impact on our operating results. We serve customers globally across a broad geographic base. Neither Russia nor Ukraine has comprised or is expected to comprise a material portion of our total revenue, net loss, or net assets. We continue to closely monitor the ongoing conflict and related sanctions, which could impact our financial results in the future. Other impacts due to this evolving situation are currently unknown and could potentially subject our business to adverse consequences should the situation escalate beyond its current scope. For additional information about the conflict between Russia and Ukraine and its potential effect on our business and results of operations, see risk factors "—The global macroeconomic environment could negatively impact our business, our financial position and our results of operations" and "—Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation" under the heading "Risks related to our business and strategy" in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K.

Impact of COVID-19

While we expect COVID-19 may continue to impact our business, we have experienced limited disruption since 2020. We have reviewed and adjusted, when necessary, for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

In response to the pandemic, we have implemented measures to protect the health of all of our employees during this time with additional measures in place to better protect our on-site lab production and support teams. Our production facilities currently remain fully operational. Substantially all of the Company's offices have re-opened in a hybrid working model, subject to operating restrictions which adhere to healthcare guidelines to protect public health and the health and safety of employees. We continue to monitor, update and align our corporate policies to meet state and federal occupational health and safety rules. While we have not experienced significant disruption in our supply

chain, we have experienced supply delays as a result of the COVID-19 pandemic and have also had to obtain supplies from new suppliers.

As a result of government-imposed restrictions, many announced healthcare guidelines resulted in a shift of regular physician visits and healthcare delivery activities to remote/telehealth formats. This is particularly important for patients who, despite the fall-out from COVID-19, continued to be diagnosed with critical diseases, like cancer, and for women who are pregnant or are trying to conceive. We believe our investments in new access platforms and technologies position us well to provide a range of testing to clinicians and patients using a "clinical care from afar" model. An example is our rollout in April 2020 of our Gia telehealth platform, which expands access to remote interaction between patients and clinicians as well as direct ordering of genetic tests.

Although many government-imposed restrictions have been reduced or eliminated, the future impact of the COVID-19 pandemic continues to be highly uncertain. Given the unknown duration and extent of COVID-19's impact on our business, and the healthcare system in general, we continue to monitor evolving market conditions and have pivoted our focus and investments on the commercial execution of workflows that support remote ordering, online support and telehealth.

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was signed into law as a stimulus bill intended to bolster the economy, among other things, and provide assistance to qualifying businesses and individuals. The CARES Act included an infusion of funds into the healthcare system. In April 2020, we received \$3.8 million as a part of this initiative, and in January 2021, we received an additional \$2.3 million. These payments were recognized as other income, net in our consolidated statements of operations in the periods received.

Adverse macroeconomic conditions

Adverse macroeconomic developments, including inflation, slowing growth, rising interest rates, or recession, may adversely affect our business and financial condition. These developments have caused, and could in the future cause, disruptions and volatility in global financial markets and increased rates of default and bankruptcy, and negatively affect business and consumer spending. Adverse economic conditions may also increase the costs of operating our business, including vendor, supplier and workforce expenses, and may limit our access to capital or may significantly increase our cost of capital. Management continues to evaluate the impact of macroeconomic events, including inflation, on our business and our future plans and intends to take appropriate measures to help alleviate their impact, but there can be no assurance that these efforts will be successful.

Factors affecting our performance

Number of billable units

Our test revenue is tied to the number of tests which we bill patients, third-party payers that pay on behalf of patients, and institutions (e.g., hospitals, clinics, medical centers, biopharmaceutical partners). We refer to the set of reagents needed to perform an NGS test for our RUO product as a "reaction," and we refer to billable events that include individual test reports released and individual reactions shipped as billable units. We typically bill for our services following delivery of the billable report derived from testing samples and interpreting the results. For units manufactured for use by customers in distributed facilities, we typically bill customers upon shipment of those units. Test orders are placed under signed requisitions or contractual agreements, as we often enter into contracts with insurance companies and institutions. We incur the expenses associated with a unit in the period in which the unit is processed regardless of when payment is received with respect to that unit. We believe the number of billable units in any period is an important indicator of the growth in our testing business, and with time, this will translate into the number of customers accessing our platform.

Number and size of research and commercial partnerships

Pharma development services revenue, which we recognize within other revenue in our consolidated statements of operations, is generated primarily from services provided to biopharmaceutical companies and other partners and is related to companion diagnostic development, clinical research, and clinical trial services across the research, development, and commercialization phases of collaborations. The result of these relationships may include the development of new targeted companion diagnostics, which underscore and expand the need for genetic testing and in some cases may lead to intellectual property and/or revenue sharing opportunities with third-party partners. As a result of the strategic realignment, we terminated early or changed the scope of certain collaborations as part of our pharma development services, and are in the process of supporting wind-down activities for certain companion diagnostic development agreements to conclude existing contracts.

Success obtaining and maintaining reimbursement

Our ability to increase volume and revenue will depend in part on our success in achieving broad reimbursement coverage and laboratory service contracts for our tests from third-party payers and agreements with institutions and partners. Reimbursement may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary and cost-effective, as well as whether we are in contract, where we get paid more consistently and at higher rates. Because each payer makes its own decision as to whether to establish a policy or enter into a contract to reimburse for our testing services and specific tests, seeking these approvals is a time-consuming and costly process. In addition, clinicians and patients may decide not to order our tests if the cost of the test is not covered by insurance. Because we require an ordering physician to requisition a test, our revenue growth also depends on our ability to successfully promote the adoption of our testing services and expand our base of ordering clinicians. We believe that establishing coverage and obtaining contracts from third-party payers is an important factor in gaining adoption by ordering clinicians. Our arrangements for laboratory services with payers cover approximately 332 million lives, including Medicare, all national commercial health plans, and Medicaid in most states, including California (Medi-Cal), our home state.

Ability to lower the costs associated with performing our tests

Reducing the costs associated with performing our genetic tests is both a focus and a strategic objective of ours. Over the long term, we will need to reduce the cost of raw materials by improving the output efficiency of our assays and laboratory processes, modifying our platform-agnostic assays and laboratory processes to use materials and technologies that provide equal or greater quality at lower cost, improve how we manage our materials, port some tests onto a next generation sequencing platform and negotiate favorable terms for our materials purchases. We also intend to continue to design and implement hardware and software tools that are designed to reduce personnel-related costs for both laboratory and clinical operations/medical interpretation by increasing personnel efficiency and thus lowering labor costs per test.

Ability to optimize our genetic content in meeting market needs and create new pathways to test

We intend to continue to reduce the average cost per test, optimize our test menus and content, and offer the tests at affordable prices in order to meet customer and patient needs. In addition, we have and intend to continue to identify new ways to connect our testing services and information to patients. These include direct patient outreach and ordering capacity, the use of automated assistants for physician customers to improve the ease of ordering and processing genetic tests and programs designed to reach underserved patient populations with genetic testing. We also continue to collaborate with strategic partners and identify new market and channel opportunities.

Realignment of our business and timing of expenses

As part of the strategic realignment of our operations announced in July 2022, we initiated a comprehensive plan focused on supporting business lines and geographies that we believe can generate sustainable margins, provide the best return to fuel future investment and accelerate the Company's path to positive cash flow. We believe the plan further helps ensure we remain at the forefront of innovation and advancements in genomics by allocating resources towards our core genetic testing and data and patient network platform that have the potential to improve healthcare outcomes.

We conducted an assessment of our product portfolio as well as the associated research and development and commercial spending. Our plan shifts the focus to programs relevant to the core testing business to drive profitable growth. We also performed an extensive review of internal and external costs and how those expenses align with the business structure. Additional savings are expected to be generated through the ongoing digitization of workflows, elimination of duplication and streamlined processes across the core platforms and rationalization of technology and external services.

As we refocus our operations on our core genomic testing platform, we also plan to continue to invest in our genetic testing and data business to drive long-term profitable growth. We deploy state-of-the-art technologies in our genetic testing services, and we intend to continue to scale our infrastructure, including our testing capacity and capabilities as well as our information systems. We also expect to incur software development costs as we seek to further digitize and automate our laboratory processes and our genetic interpretation and report sign-out procedures, scale our customer service capabilities to improve our clients' experience, and expand the functionality of our website. We will continue to incur costs related to marketing and branding as we expand our initiatives beyond our current customer base and focus on providing access to customers through our website. In addition, we will incur ongoing expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter as we focus on building out different aspects of our business.

How we recognize revenue

We generally recognize revenue on an accrual basis, which is when a customer obtains control of the promised goods or services, typically a test report, or upon shipment of our precision oncology products. Accrual amounts recognized are based on estimates of the consideration that we expect to receive, and such estimates are adjusted and subsequently recorded until fully settled. Changes to such estimates may increase or decrease revenue recognized in future periods. Revenue from our tests may not be equal to billed amounts due to a number of factors, including differences in reimbursement rates, the amounts of patient payments, the existence of secondary payers and claim denials. Some test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with insurance companies and institutions that include pricing provisions under which such tests are billed.

Pharma development service revenue is generated primarily from custom assay design services, sample processing activities and consultative inputs, which is separate from revenue generated by any related or unrelated product component. Subsequent to the strategic realignment, pharma development service revenue is generated from personalized cancer monitoring services and sample processing activities. Revenue is recognized as services are provided using the input method based on our assessment of performance completed to date toward completion of a contract.

Financial overview

Revenue

We primarily generate revenue from testing services and sales of distributed precision oncology products. Customers are typically billed upon delivery of test results or shipment of products. We also generate revenue from development agreements, access to data, data analytics and other related services provided for biopharmaceutical partners and other parties. Our ability to increase our revenue will depend on our ability to increase our market penetration, obtain contracted reimbursement coverage from third-party payers and increase the amount we receive from other types of payers, improve payer collections, and grow our relationships with biopharma partners.

As a result of the strategic realignment, we exited certain product lines including our distributed precision oncology products and terminated early or changed the scope of certain collaborations as part of our pharma development services. We are in the process of supporting wind-down activities for certain companion diagnostic development agreements to conclude existing contracts.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering our products and services and includes expenses for materials and supplies, personnel-related costs, freight, costs for lab services, genetic interpretation and clinical trial support, equipment and infrastructure expenses and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangibles, and utilities. We expect cost of revenue to generally increase in line with an increase in billable volume. We also expect amortization of acquired intangible assets, which is not dependent on billed volume, to remain consistent with 2022 expenses. We anticipate our cost per unit for existing tests will generally decrease over time due to the efficiencies we expect to gain as volume increases, and from other cost reductions achieved through automation, supply chain and logistics initiatives, process standardization, and other cost reductions. These reductions in cost per unit will likely be offset by new offerings, which often have a higher costs per unit during the introductory phases before we are able to gain efficiencies. The cost per unit may fluctuate significantly from quarter to quarter.

Operating expenses

Our operating expenses are classified into three categories related to our operational activities: research and development, selling and marketing, and general and administrative. For each category, the largest component is generally personnel-related costs, which include salaries, employee benefit costs, bonuses, commissions, as applicable, and stock-based compensation expense. Operating expense categories also include goodwill and IPR&D impairment, restructuring and other costs, gain on sale of RUO kit assets, and change in fair value of contingent consideration, which are discussed further below.

Research and development

Research and development expenses represent costs incurred to develop our technology and future offerings. These costs are principally for process development associated with our efforts to expand the number of genes we

can evaluate, our efforts to lower the costs per unit and our development of new products to expand our platform. We have and may continue to partner with other companies to develop new technologies and capabilities we expect to invest capital and incur significant operating costs to support these development efforts. In addition, we incur process development costs to further develop the software we use to operate our laboratories, analyze generated data, process customer orders, validate clinical activities, enable ease of customer ordering, deliver reports and automate our business processes. These costs consist of personnel-related costs, laboratory supplies and equipment expenses, consulting costs, amortization of acquired intangible assets, and allocated overhead including rent, information technology, equipment depreciation and utilities.

We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to decrease as we streamline our product portfolio, shift investments, including the exit of certain business lines and commercial geographies, and reduce labor costs through a reduction in workforce. We expect to make investments to reduce costs and streamline our technology to provide patients access to testing aligned to scale with our long-term profitable growth targets.

During October 2020 through our acquisition of ArcherDX, we recognized \$512.4 million of IPR&D technology for two assets representing a therapy selection IVD and PCM technologies, both using an income approach. During the year ended December 31, 2022, the IVD and PCM products were fully developed resulting in the reclassification of the related IPR&D intangibles to developed technology intangibles, which are finite-lived and amortizable.

Selling and marketing

Selling and marketing expenses consist of personnel-related costs, including commissions, client service expenses, advertising and marketing expenses, educational and promotional expenses, market research and analysis, and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangibles, and utilities. We expect our selling and marketing expenses to decrease as a result of a reduction in workforce, targeted sales force expansion and lower marketing spending as we implement a more efficient sales and marketing approach to support our core genetic testing platform.

General and administrative

General and administrative expenses include executive, finance and accounting, billing and collections, legal and human resources functions as well as other administrative costs. These expenses include personnel-related costs; audit, accounting and legal expenses; consulting costs; allocated overhead including rent, information technology, equipment depreciation, and utilities; costs incurred in relation to our co-development agreements; and post-combination expenses incurred in relation to companies we acquire. We expect our general and administrative expenses to decrease as a result of our strategic realignment including a reduction in workforce, consolidation of underutilized facilities, digitization of workflows, elimination of duplication and streamlined processes, and rationalization of technology and external services spending.

Goodwill and IPR&D impairment

Goodwill and IPR&D impairment expenses include the impairment loss recognized on goodwill and the IPR&D indefinite-lived intangible asset initially recognized as part of the acquisition of Singular Bio. Goodwill and indefinite-lived intangible assets are assessed for impairment on an annual basis and whenever events and circumstances indicate that these assets may be impaired. We compare the fair value of our reporting unit to its carrying value, including goodwill. If the carrying value, including goodwill, exceeds the reporting unit's fair value, we will recognize an impairment loss for the amount by which the carrying amount exceeds the reporting unit's fair value.

Restructuring and other costs

Restructuring and other costs includes employee severance and benefits, assets impairments and losses on asset disposals and other costs. Employee separation costs are comprised of severance, other termination benefit costs, and stock-based compensation expense for the acceleration of RSUs related to workforce reductions. Employee separation costs include one-time termination benefits that are recognized as a liability at estimated fair value, at the time of communication to employees, unless future service is required, in which case the costs are recognized ratably over the future service period. Ongoing termination benefits are recognized as a liability at estimated fair value when the amount of such benefits is probable and reasonably estimable. Asset impairments and losses on asset disposals include operating lease impairments, losses on disposals of property and equipment and leasehold improvements associated with exiting lines of business, consolidating lab and office space, and reducing our international footprint. Other restructuring costs include the write-off of prepayments made to certain vendors for which we will no longer benefit from those goods or services, legal and professional fees, and contract exit costs.

Gain on sale of RUO kit assets

The gain on the sale of the RUO kit assets consists of the consideration received including up front consideration subject to a hold-back to satisfy indemnification obligations that may arise.

Change in fair value of contingent consideration

Changes in fair value of contingent consideration are adjustments to contingent consideration related to business combinations. We did not complete any acquisitions in fiscal year 2022, which has reduced our contingent liability balance as of December 31, 2022 and the associated change in fair value of contingent consideration for the year ended December 31, 2022. We expect future fair value changes to fluctuate from period to period due to fair value adjustments that are dependent on many factors, including no new acquisitions in 2022, the value of our common stock and our assessment of the probability of meeting certain acquisition-related milestones within the terms of the respective acquisition agreements, including certain prescribed deadlines for achievement.

With respect to the ArcherDX final milestone, the liability was reduced to zero as of as of June 30, 2021, with the offsetting change recorded as changes in fair value of contingent consideration in our consolidated statements of operations. The removal of the liability balance and the associated change in fair value of contingent consideration was a result of our reassessment of the steps necessary to achieve clearance or approval based on FDA feedback received principally in the three months ended June 30, 2021. In April 2022, an agreement was entered into with previous ArcherDX stockholders to extend the date of achievement of the ArcherDX final milestone to March 31, 2023. We currently do not believe that this milestone will be achieved within this timeframe. As such, no liability was recorded as of December 31, 2022 or 2021.

Other income (expense), net

Other income (expense), net, primarily consists of adjustments to the fair value of our acquisition-related liabilities and interest income. Acquisition-related liabilities include stock payable liabilities arising from business combinations, and we expect the adjustments to fluctuate from period to period primarily due to the volatility of our common stock. Other income (expense), net also includes income generated from our cash equivalents and marketable securities and amounts received under the CARES Act.

Interest expense

Interest expense is primarily attributable to interest incurred related to our debt financings and finance leases. See Note 8, "Commitments and contingencies" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information.

Income tax benefit

Since we generally establish a full valuation allowance against our deferred tax assets, our income tax benefit primarily consists of changes in our deferred tax realization assessments as a result of taxable temporary differences assumed in connection with our acquisitions and changes in the expected timing of the reversal of taxable temporary differences.

Critical accounting policies and estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. We evaluate our estimates on an ongoing basis. Our estimates are based on current facts, our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that our accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue recognition

We recognize revenue when or as control of the promised goods or services is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers. We utilize the following practical expedients and exemptions:

- Costs to obtain or fulfill a contract are expensed when incurred because the amortization period would have been one year or less, and
- No adjustments to promised consideration were made for financing as we expect, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

Test revenue

Test revenue is comprised of testing services and sales of distributed precision oncology products.

The majority of our test revenue is generated from genetic testing, in addition to somatic testing for therapy selection and personalized cancer monitoring. These testing services provide analysis and associated interpretation of the sequencing of parts of the genome. Test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with insurance companies and institutions that include pricing provisions under which such tests are billed. Billing terms are generally net 30 to 60 days.

While the transaction price of diagnostic tests is originally established either via contract or pursuant to our standard list price, we often provide price concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which we will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur. Making these estimates requires significant judgments based upon such factors as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. These judgments are reviewed each reporting period and updated as necessary.

We look to transfer of control in assessing timing of recognition of revenue in connection with each performance obligation. In general, revenue in connection with the service portion of our diagnostic tests is recognized upon delivery of the underlying clinical report or when the report is made available on our web portal. Outstanding performance obligations pertaining to orders received but for which the underlying report has not been issued are generally satisfied within a 30-day period.

We also generated test revenue through the sale of our distributed precision oncology products, which is comprised primarily of sales of our RUO kit and IVD product offerings for therapy selection. We recognized revenue on these sales once shipment had occurred. Product sales were recorded net of discounts and other deductions. Billing terms were generally net 30 days. As part of the strategic realignment, we exited these product offerings in fiscal year 2022. See Note 4, "Business combinations and dispositions" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information on the disposition of the RUO kit assets. See Note 5, "Goodwill and intangible assets" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information on the exit of the IVD product offering.

Shipping and handling fees billed to customers are recorded as revenue in the consolidated statements of operations. The associated shipping and handling costs are recorded in cost of revenue.

Other revenue

Other revenue is primarily generated from collaboration agreements and genome network contracts as well as pharma development services provided to biopharmaceutical companies related to companion diagnostic development.

We enter into collaboration and genome network contracts. Collaboration agreements provide customers with diagnostic testing and related data aggregation reporting services that are provided over the contract term. Collaboration revenue is recognized as the data and reporting services are delivered to the customer. Genome network offerings consist of subscription services related to a proprietary software platform designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis and treatment of hereditary disease. Such services are recognized on a straight-line basis over the subscription periods. Amounts due under collaboration and genome network agreements are typically billable on net 30-day terms.

Contracts for companion diagnostic development consisted primarily of milestone-based payments along with annual fees and marked-up pass-through costs. The arrangements were treated as short-term contracts for revenue recognition purposes because they allow termination of the agreements by the customers with 30 to 120 days' written notice without a termination penalty. Upon termination, customers were required to pay for the proportion of services provided under milestones that were in progress. We recognized revenue in an amount that reflected the consideration which we expect to receive in exchange for those goods or services. We recognized revenue as services are provided based on the progress made toward achieving the performance obligation, utilizing input methods, including labor hours expended and tests processed, that measure our progress toward the achievement of the milestone.

Business combinations

We apply Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") 805, *Business Combinations*, which requires recognition of assets acquired, liabilities assumed, and contingent consideration at their fair value on the acquisition date with subsequent changes recognized in earnings; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination and expensed as incurred; requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset until completion or abandonment; and requires that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of provision for taxes.

We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. We base the estimated fair value of identifiable intangible assets acquired in a business combination on third-party valuations that use information and assumptions provided by our management, which consider our estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, estimated cost savings, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under ASC 480, *Distinguishing Liabilities from Equity*, we recognize a liability equal to the fair value of the contingent payments we expect to make as of the acquisition date. We remeasure this liability each reporting period and record changes in the fair value in change in fair value of contingent consideration in our consolidated statements of operations.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in our operating results from the date of acquisition.

Asset acquisitions

In circumstances where substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the asset is not considered a business and we account for the transaction as an asset acquisition. We recognize the assets acquired based on their relative fair value, which generally includes the transaction costs of the asset acquisition, and no gain or loss is recognized unless the fair value of noncash assets given as consideration differs from the assets' carrying amounts. The form of consideration transferred may be cash, liabilities incurred, or equity interests issued.

Goodwill and indefinite lived intangibles

In accordance with ASC 350, *Intangibles - Goodwill and Other* we do not amortize goodwill or other intangible assets with indefinite lives, including in-process research and development, but rather test them for impairment. ASC 350 requires us to perform an impairment review of our goodwill balance at least annually, which we do in the fourth quarter of each year for our single consolidated reporting unit, and whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable.

Factors that may indicate potential impairment and trigger an interim impairment test include, but are not limited to, current economic, market and geopolitical conditions, including a significant, sustained decline in our stock price and market capitalization compared to the net book value, an adverse change in legal factors, business climate or operational performance of the business, or significant changes in the ability of a particular asset (or group of assets) to generate positive cash flows for our strategic business objectives. During the three months ended June 30, 2022, as a result of significant, sustained decline in our stock price and related market capitalization and lower than expected financial performance, we performed an impairment assessment of goodwill, IPR&D intangibles, and long-lived assets, including definite-lived intangibles.

In the quarter ended June 30, 2022, the Company completed a quantitative impairment test for goodwill. In performing the goodwill impairment test, we estimated the fair value of the reporting unit by utilizing the discounted cash flow method under the income approach. The determination of the fair value of the reporting unit requires significant estimates and assumptions, including significant unobservable inputs. The key inputs to this valuation approach include, but were not limited to, management's forecast of projected revenues associated with future cash flows, discount rates, and control premiums.

When performing our income approach for the reporting unit, we incorporate the use of projected financial information and a discount rate that is developed using market participant-based assumptions. The cash flow projections are based on an 11-year financial forecast developed by management that includes projections of billable units, revenue by test type and mix, rate changes, capital spending trends, investments in working capital to support future revenue and projected cash flow sources and needs, among others. The selected discount rate then considers the risk and nature of the reporting unit's cash flows and rates of return market participants would require to invest capital in the reporting unit.

Based on this analysis, we recognized a goodwill impairment charge of \$2.3 billion during the quarter ended June 30, 2022, which was included in goodwill and IPR&D impairment expense in the consolidated statements of operations. This charge fully impaired the goodwill balance as of June 30, 2022.

We also identified indicators of impairment related to the IPR&D intangible asset initially recognized as part of the acquisition of Singular Bio that is more likely than not that the asset is impaired. The Company identified conditions during the quarter ended June 30, 2022 such as alternative technologies and uncertainties around the desired outcome of our in-development asset and other economic factors that raised issues with the realizability of our asset. As a result of our evaluation, we recognized an impairment charge of \$30.0 million during the quarter ended June 30, 2022. The impairment charges are recorded in goodwill and IPR&D impairment expense in the consolidated statements of operations. This charge fully impaired the indefinite-lived intangible asset balance as of June 30, 2022. We did not record any goodwill or intangible asset impairment losses during the years ended December 31, 2021 and 2020, respectively.

Impairment assessment of long-lived assets

A recoverability test was performed for the long-lived assets, including definite-lived intangibles, using the undiscounted cash flows approach, which included significant unobservable inputs including management's forecasts of projected revenue associated with future cash flows and residual value. The cash flow estimates reflected the Company's assumptions about its use of the long-lived assets and eventual disposition of the asset group. We determined that our long-lived assets held and used, including intangible assets that are subject to amortization, did not have identifiable cash flows that are largely independent of the cash flows of other assets and liabilities and of other asset groups, because the assets are highly interrelated and interdependent. Therefore, the Company evaluated its long-lived assets for impairment on an entity-wide level. As a result of the recoverability test, we concluded that the carrying value of long-lived assets was recoverable at June 30, 2022. No impairment was recorded except for operating lease impairments, which are discussed under the heading "Leases" within Note 8, "Commitments and contingencies" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report on Form 10-K. We also recorded losses on disposal of assets pursuant to the strategic realignment, which are discussed within Note 11, "Restructuring and other costs" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report on Form 10-K.

Stock-based compensation

We incur stock-based compensation expense for awards granted to employees and directors and for inducement awards granted in connection with our business acquisitions. Stock-based compensation expense is measured at the date of grant and is based on the estimated fair value of the award. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and restricted stock unit ("RSU") awards, and on an accelerated basis for performance-based restricted stock unit ("PRSU") awards. We recognize stock-based

compensation expense associated with PRSU grants when we determine the achievement of performance conditions is probable. In determining the fair value of stock options and employee stock purchase plan ("ESPP") purchases, we estimate the grant date fair value and the resulting stock-based compensation expense using the Black-Scholes option-pricing model. We estimate the grant date fair value of RSU and PRSU awards based on the grant date share price.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of stock-based awards. These assumptions include:

Fair value of common stock—The fair value of each share of common stock is based on the closing price of our common stock on the date of grant as reported on the NYSE.

Expected term—The expected term represents the period that stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is based on the mid-point between the vesting date and the end of the contractual term.

Expected volatility—We estimate expected volatility based on the historical volatility of our common stock over a period equal to the expected term of awards and over the expected six-month term ESPP purchase periods.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of an option.

Dividend yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods.

Income taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Significant judgment is required in determining the net valuation allowance which includes our evaluation of all available evidence including past operating results, estimates on future taxable income and acquisition-related tax assets and liabilities. As of December 31, 2022, we recorded a full valuation allowance on our net deferred tax assets because we expect that it is more likely than not that our net deferred tax assets will not be realized in the foreseeable future. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted.

Results of operations

A discussion regarding our financial condition and results of operations for the year ended December 31, 2022 compared to the year ended December 31, 2021 is presented below. A discussion regarding our financial condition and results of operations for the year ended December 31, 2021 compared to the year ended December 31, 2020 can be found under Part II, Item 7. in our Annual Report on Form 10-K for the year ended December 31, 2021.

Comparison of the Years Ended December 31, 2022 and 2021

	Year Ended December 31,		Dollar Change	% Change
	2022	2021		
Revenue:				
Test revenue	\$ 500,560	\$ 444,072	\$ 56,488	13%
Other revenue	15,743	16,377	(634)	(4)%
Total revenue	516,303	460,449	55,854	12%
Operating expenses:				
Cost of revenue	417,256	348,669	68,587	20%
Research and development	402,088	416,087	(13,999)	(3)%
Selling and marketing	218,881	225,910	(7,029)	(3)%
General and administrative	192,314	248,070	(55,756)	(22)%
Goodwill and IPR&D impairment	2,313,047	—	2,313,047	100%
Restructuring and other costs	140,331	—	140,331	100%
Gain on sale of RUO kit assets	(47,354)	—	(47,354)	100%
Change in fair value of contingent consideration	(1,850)	(386,646)	384,796	100%
Total operating expenses	3,634,713	852,090	2,782,623	NM
Loss from operations	(3,118,410)	(391,641)	(2,726,769)	NM
Other income (expense), net:				
Change in fair value of acquisition-related liabilities	15,906	25,196	(9,290)	(37)%
Other income, net	8,054	482	7,572	NM
Total other income, net	23,960	25,678	(1,718)	(7)%
Interest expense	(56,747)	(49,900)	(6,847)	(14)%
Net loss before taxes	(3,151,197)	(415,863)	(2,735,334)	NM
Income tax benefit	44,904	36,857	8,047	22%
Net loss	\$ (3,106,293)	\$ (379,006)	\$ (2,727,287)	NM

NM - Not Meaningful

Revenue

The increase in revenue of \$55.9 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to increased billable volume and higher average revenue per billable unit. Billable volume increased to 1,290,000 during the year ended December 31, 2022 compared to 1,169,000 in the same period in 2021, an increase of 10%, due to growth in the business. Average revenue per unit increased to \$388 during the year ended December 31, 2022 compared to \$380 in the same period in 2021 primarily due to changes in payer and product mix.

Cost of revenue

The increase in the cost of revenue of \$68.6 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to increased billable volume. For the year ended December 31, 2022, the number of units billed increased to 1,290,000 from approximately 1,169,000 for the same period in 2021. Cost per unit was \$323 in 2022 compared to \$298 in 2021. The increase in cost per unit is primarily attributable to an increase in amortization of acquired intangible assets of \$50.6 million, an increase in inventory and prepaid asset write downs of \$18.2 million principally related to the exit of certain product offerings and geographies, and an increase in shipping costs of \$6.4 million related to higher volumes and passed through increases in fuel prices. These increases were partially offset by lower lab materials costs of \$5.2 million primarily due to a decrease in the volume and change in mix of materials, and a decrease in other costs of \$1.4 million.

Research and development

The decrease in research and development expense of \$14.0 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to decreases in lab-related expenses of \$37.7 million as a result of lower costs related to external development projects and lab supplies and services, decreases in personnel-related expenses of \$19.5 million primarily due to the reduction in workforce related to our strategic realignment, and decreases in information technology costs of \$3.7 million due to lower network and cloud computing expenses. These decreases were partially offset by increases in acquisition-related compensation expenses of \$40.3 million primarily due to a full year of stock-based compensation in 2022 as compared to a partial year of expense in 2021 related to several acquisitions in the comparative period, and increases in professional fees of \$6.6 million due to higher contract labor.

Selling and marketing

The decrease in selling and marketing expenses of \$7.0 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to decreases in marketing expenses of \$10.5 million as a result of lower costs related to brand initiatives and advertising, decreases in other expenses of \$1.9 million, and decreases in professional fees of \$1.7 million due to lower contract labor. These decreases were offset by increases in personnel-related expenses of \$2.7 million driven by headcount growth in 2022 prior to our strategic realignment, increases in travel-related expenses of \$2.4 million due to more in-person travel as a result of reduced COVID-19 restrictions, and increases in information technology costs of \$2.0 million due to higher spending on software licenses.

General and administrative

The decrease in general and administrative expenses of \$55.8 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to decreases in acquisition-related compensation expense of \$49.1 million as a result of several acquisitions in the comparative period, decreases in legal fees of \$9.7 million for litigation-related expenses in the comparative period, and decreases in personnel-related costs of \$7.1 million primarily due to the reduction in workforce related to our strategic realignment. These decreases were partially offset by increases in other corporate expenses of \$6.3 million in 2022 prior to our strategic realignment, and increases in facilities-related expenses of \$3.8 million due to lease expenses and higher security and building support costs.

Goodwill and IPR&D impairment

We completed an interim impairment test for goodwill and the IPR&D indefinite-lived intangible asset as of June 30, 2022, and as a result recorded a non-cash impairment charge of \$2.3 billion. See Critical accounting policies and estimates above and Note 5, "Goodwill and intangible assets" in Notes to the Consolidated Financial Statements in Part II, Item 8. "Consolidated Financial Statements" of this Annual Report on Form 10-K for further information.

Restructuring and other costs

During the year ended December 31, 2022, we incurred restructuring and other costs of \$140.3 million. Restructuring and other costs were comprised of \$65.5 million in employee severance and benefits, \$60.5 million in asset impairments and losses on asset disposals, and \$14.3 million in other restructuring expenses. We did not have similar expenses for the year ended December 31, 2021. See Note 11, "Restructuring and other costs" in Notes to the Consolidated Financial Statements in Part II, Item 8. "Consolidated Financial Statements" of this Annual Report on Form 10-K for further information.

Gain on sale of RUO kit assets

During the year ended December 31, 2022, we completed the sale and transfer to IDT of select assets and liabilities related to the RUO kit product offering, which represents the RUO distributed target enrichment kit and data analysis platform of ArcherDX. After adjustments, the sale resulted in a gain of approximately \$47.4 million for the year ended December 31, 2022. We did not have a similar gain for the year ended December 31, 2021. See Note 4, "Business combinations and dispositions" in Notes to the Consolidated Financial Statements in Part II, Item 8. "Consolidated Financial Statements" of this Annual Report on Form 10-K for further information.

Change in fair value of contingent consideration

The change in fair value of contingent consideration represented income of \$1.9 million and \$386.6 million for the years ended December 31, 2022 and 2021, respectively. The year ended December 31, 2022 includes fair value adjustments to reduce our contingent consideration liability related to the acquisition of Genelex Solutions, LLC

("Genelex") and the achievement of certain product milestones related to gross revenues received by us for a pharmacogenetic product reimbursed through certain payers during the earn-out period. The adjustment to decrease our contingent consideration liability primarily related to the probability of achieving gross revenue reimbursements during the earn-out period. The year ended December 31, 2021 includes fair value adjustments to reduce our contingent consideration liability primarily related to our acquisition of ArcherDX and the remaining development milestones resulting from a decrease in the value of our common stock. The prior year adjustments to decrease our contingent consideration were due to our determination that our outstanding milestone for FDA clearance or approval of a therapy selection IVD will not be achieved in the timeframe prescribed in the acquisition agreement.

Change in fair value of acquisition-related liabilities

The decrease in change in fair value of acquisition-related liabilities of \$9.3 million for the year ended December 31, 2022 compared to the same period in 2021 was due to a decrease in fair value adjustments related to our stock payable as a result of the decrease in the price of our common stock and settlement of acquisition-related hold-backs.

Other income, net

The increase in other income, net of \$7.6 million for the year ended December 31, 2022 compared to the same period in 2021 was due to an increase in interest income earned on our marketable securities investments.

Interest expense

The increase in interest expense of \$6.8 million for the year ended December 31, 2022 compared to the same period in 2021 was principally due to increased debt outstanding during 2022 as compared to the prior year.

Income tax benefit

The increase in income tax benefit of \$8.0 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to the release of federal and state valuation allowances as a result of the reclassification of the IVD and PCM in-process research and development intangibles from indefinite-lived intangibles to developed technology, which enabled the associated deferred tax liability to serve as a source of income to existing finite-lived deferred tax assets for which a valuation allowance had previously been established. There was no similar income tax benefit for the year ended December 31, 2021.

Liquidity and capital resources

Liquidity and capital expenditures

We have generally incurred net losses since our inception. For the years ended December 31, 2022, 2021 and 2020, our net losses were \$3.1 billion, \$379.0 million and \$602.2 million, respectively, and we expect to incur additional losses in the future. At December 31, 2022, we had an accumulated deficit of \$4.8 billion. While our revenue has increased over time, we may never achieve revenue sufficient to offset our expenses.

Since inception, our operations have been financed primarily by fees collected from our customers, net proceeds from sales of our capital stock as well as borrowing from debt facilities and the issuance of convertible senior notes.

In January 2021, we issued, in an underwritten public offering, an aggregate of 8.9 million shares of our common stock at a price of \$51.50 per share, for gross proceeds of \$460.0 million and net proceeds of approximately \$434.3 million. In April 2020, we issued, in an underwritten public offering, an aggregate of 20.4 million shares of our common stock at a price of \$9.00 per share, for gross proceeds of \$184.0 million and net proceeds of \$173.0 million. In 2022, we issued 2.4 million shares of common stock at an average price of \$3.99 per share in an "at the market" offering for aggregate proceeds of \$10.0 million and net proceeds of \$9.7 million. In 2020, we issued 3.6 million shares of common stock at an average price of \$26.33 per share in an "at the market" offering for aggregate proceeds of \$93.7 million and net proceeds of \$90.7 million.

In September 2019, we issued \$350.0 million of aggregate principal amount of convertible senior notes due 2024, which bear cash interest at a rate of 2.0% per year. Also in September 2019, we used the funds received through the issuance of our convertible senior notes due 2024 to settle our note purchase agreement we entered into in November 2018. In April 2021, we issued \$1,150.0 million of aggregate principal amount of convertible senior notes due 2028, which bear cash interest at a rate of 1.5% per year. Our business may not generate cash flow from operations in the future sufficient to service our debt, including paying off the principal when due, and make necessary

capital expenditures. Holders of our convertible senior notes have the right to require us to repurchase all or any portion of their notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments, which could adversely affect our liquidity. However, we only have limited ability to make those cash payments under our credit agreement and, even if the credit agreement limitations are no longer in effect, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of notes surrendered or to repay outstanding notes when they mature.

In October 2020, in connection with our acquisition of ArcherDX, we issued \$275.0 million of our common stock in a private placement at a price of \$16.85 per share. We also entered into a credit agreement to borrow \$135.0 million. The private placement and credit agreement closed concurrently with the merger in October 2020. The terms of this credit agreement restrict our ability to incur certain indebtedness, pay dividends, make acquisitions and take other actions. On February 7, 2023, we made a \$53.7 million payment which reduced the principal balance of the 2020 Term Loan by \$50.0 million and included a \$3.0 million prepayment fee, with the remainder attributable to interest. On February 28, 2023, we repaid the remaining principal balance outstanding of \$85.0 million plus outstanding interest of \$1.9 million and a prepayment fee of \$5.1 million. See Note 16, "Subsequent events" in Notes to the Consolidated Financial Statements in Part II, Item 8. "Consolidated Financial Statements" of this Annual Report on Form 10-K for further information.

At December 31, 2022 and 2021, we had \$557.1 million and \$1.1 billion, respectively, of cash, cash equivalents, restricted cash and marketable securities.

Our primary uses of cash are to fund our operations. Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We estimate our capital expenditures will be approximately \$10.0 to \$15.0 million for 2023.

We have incurred substantial losses since inception, and we expect to continue to incur losses in the near future. We believe our existing cash, cash equivalents and marketable securities as of December 31, 2022 and fees collected from the sale of our products and services will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

We expect to raise additional funding to finance operations and service debt obligations prior to achieving profitability or should we make additional acquisitions. We regularly consider fundraising opportunities and expect to determine the timing, nature and size of future financings based upon various factors, including market conditions, debt maturities and our operating plans. We may in the future elect to finance operations by selling equity or debt securities or borrowing money. If we issue equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing additional debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. In addition, the terms of additional debt securities or borrowings could impose significant restrictions on our operations. If additional funding is required, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all. If we are unable to obtain additional funding when needed, we may need to curtail planned activities to reduce costs. Doing so will likely have an unfavorable effect on our ability to execute on our business plan and have an adverse effect on our business, results of operations and future prospects.

The following table summarizes our cash flows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Cash used in operating activities	\$ (492,961)	\$ (559,815)	\$ (298,502)
Cash used in investing activities	(174,803)	(204,080)	(400,583)
Cash provided by financing activities	1,758	1,565,940	672,993
Net (decrease) increase in cash, cash equivalents and restricted cash	\$ (666,006)	\$ 802,045	\$ (26,092)

Cash flows from operating activities

For the year ended December 31, 2022, cash used in operating activities was \$493.0 million and principally resulted from our net loss of \$3.1 billion, a \$47.4 million gain on the sale of the RUO kit assets, a \$44.9 million income tax benefit, non-cash charges for remeasurements of liabilities in connection with business combinations of \$17.8 million, and \$1.5 million of amortization of premiums on investment securities. These were partially offset by non-cash

charges of \$2.3 billion for goodwill and IPR&D impairments, \$199.3 million for stock-based compensation, \$142.1 million for depreciation and amortization, \$60.5 million related to impairments and losses on disposals of long-lived assets related to our strategic realignment, \$15.6 million for amortization of debt discount and issuance costs related to our outstanding debt, \$10.2 million of non-cash lease expense, \$8.4 million of post-combination deferred compensation expense, and \$1.0 million of other adjustments. The net effect on cash for changes in net operating assets was a decrease of cash of \$25.3 million due principally to increases in accounts receivable due to timing of collections, inventory and accounts payable, partially offset by increases in accrued liabilities.

For the year ended December 31, 2021, cash used in operating activities was \$559.8 million and principally resulted from our net loss of \$379.0 million, non-cash charges for remeasurements of liabilities associated with business combinations of \$411.8 million primarily related to ArcherDX development milestones, and a \$36.9 million income tax benefit primarily generated from our acquisitions of One Codex, Genosity, Ciitizen and Stratify. These were partially offset by non-cash charges of \$180.1 million for stock-based compensation, \$80.5 million for depreciation and amortization, \$14.2 million for amortization of debt discount and issuance costs related to our outstanding debt, \$9.5 million of post-combination expense primarily comprised of hold-back cash consideration related to our acquisition of Ciitizen and the acceleration of unvested equity from our acquisition of One Codex, \$6.2 million of amortization of premiums on investment securities, \$3.5 million of non-cash lease expense, and \$1.5 million of other adjustments. The net effect on cash for changes in net operating assets was a decrease of cash of \$27.6 million due principally to increases in accounts receivable due to timing of collections, inventory and accounts payable, partially offset by increases in accrued liabilities.

For the year ended December 31, 2020, cash used in operating activities was \$298.5 million and principally resulted from our net loss of \$602.2 million and \$112.1 million related to our income tax benefit generated from business combinations completed in 2020, partially offset by noncash charges of \$158.7 million for stock-based compensation, \$92.3 million in remeasurements of liabilities associated with business combinations such as contingent consideration, \$91.0 million related to post-combination expense due to the acceleration of unvested equity in the acquisition of ArcherDX, \$39.1 million for depreciation and amortization, \$17.2 million of amortization of debt discount and issuance costs, \$1.2 million of amortization premiums on investment securities, and \$0.2 million of other adjustments. The net effect on cash for changes in net operating assets was an inflow of cash of \$16.0 million due principally to increases in accounts payable and accrued liabilities, partially offset by increases in inventory and accounts receivable due to timing of collections.

Cash flows from investing activities

For the year ended December 31, 2022, cash used in investing activities of \$174.8 million was primarily due to net purchases and maturities of marketable securities of \$166.0 million and cash used for purchases of property and equipment of \$53.3 million, partially offset by proceeds from the sale of the RUO kit assets of \$44.5 million.

For the year ended December 31, 2021, cash used in investing activities of \$204.1 million was primarily due to net cash used to acquire One Codex, Genosity and Ciitizen of \$247.4 million, and cash used for purchases of property and equipment of \$54.7 million, partially offset by proceeds from net maturities and purchases of marketable securities of \$99.3 million.

For the year ended December 31, 2020, cash used in investing activities of \$400.6 million was primarily related to net cash used to acquire Orbicule BV ("Diploid"), Genelex, YouScript and ArcherDX of \$383.8 million, purchases of property and equipment of \$22.9 million, and other cash outflows of \$4.0 million, all partially offset by net sales and maturities of marketable securities of \$10.1 million.

Cash flows from financing activities

For the year ended December 31, 2022, cash provided by financing activities of \$1.8 million primarily consisted of cash received from net proceeds from the sale of common stock of \$9.7 million and issuances of common stock of \$8.1 million. These were partially offset by cash used to settle acquisition obligations of \$10.6 million and finance lease principal payments of \$5.4 million.

For the year ended December 31, 2021, cash provided by financing activities of \$1.6 billion primarily consisted of net proceeds from the issuance of convertible senior notes due 2024 of \$1.1 billion and the public offering of common stock of \$434.3 million as well as cash received from issuances of common stock totaling \$23.8 million.

For the year ended December 31, 2020, cash provided by financing activities of \$673.0 million consisted of cash received from issuances of common stock totaling \$284.2 million, including cash received from shares issued through a private placement in October 2020 upon the close of the ArcherDX acquisition, exercises of stock options and employee stock plan purchases, net proceeds from the public offerings of common stock of \$263.7 million, and

net proceeds from debt financings of \$129.2 million. These cash inflows were partially offset by other cash outflows of \$4.1 million.

Contractual obligations

The following table summarizes our contractual obligations, including interest, as of December 31, 2022 (in thousands):

Contractual obligations:	2023	2024 and 2025	2026 and 2027	2028 and beyond	Total
Operating leases	\$ 23,691	\$ 45,773	\$ 39,852	\$ 91,177	\$ 200,493
Finance leases	5,595	3,839	—	—	9,434
Convertible senior notes	—	349,996	—	1,150,000	1,499,996
2020 Term Loan	—	135,000	—	—	135,000
Purchase commitments	19,756	12,909	750	—	33,415
Total	\$ 49,042	\$ 547,517	\$ 40,602	\$ 1,241,177	\$ 1,878,338

Operating lease maturity amounts included in the table above do not include sublease income expected to be received under our sublease with IDT. Under the sublease agreement, we expect to receive sublease income for fiscal years ending December 31, 2023, 2024 and 2025 of \$0.9 million, \$0.9 million and \$0.1 million, respectively.

See Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report for additional details regarding our leases, convertible senior notes, 2020 Term Loan and purchase commitments.

Off-balance sheet arrangements

We have not entered into any off-balance sheet arrangements.

Recent accounting pronouncements

See "Recent accounting pronouncements" in Note 2, "Summary of significant accounting policies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report for a discussion of recently adopted accounting pronouncements and accounting pronouncements not yet adopted, and their expected effect on our financial position and results of operations.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. Our cash, cash equivalents, restricted cash and marketable securities totaled \$557.1 million at December 31, 2022, and consisted primarily of bank deposits, money market funds, U.S. Treasury notes and U.S. government agency securities. Such interest-bearing instruments carry a degree of risk; however, because our investments are primarily high-quality credit instruments with short-term durations with high-quality institutions, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. At December 31, 2022, a hypothetical 1.0% (100 basis points) increase or decrease in interest rates would not have resulted in a material change in the fair value of our cash equivalents and marketable securities. Fluctuations in the value of our cash equivalents and marketable securities caused by a change in interest rates (gains or losses on the carrying value) are recorded in other comprehensive gain (loss) and are realized if we sell the underlying securities prior to maturity.

Our 2020 Term Loan bears interest at an annual rate equal to three-month LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75% and is therefore sensitive to changes in interest rates. If three-month LIBOR can no longer be determined or if the applicable governmental authority ceases to supervise or sanction such rates, then we will endeavor to agree with the administrative agent, an alternate rate of interest that gives due consideration to the then prevailing market convention for determining interest for comparable loans in the United States; provided that until such alternative rate of interest is agreed, the 2020 Term Loan shall bear interest at the *Wall Street Journal* Prime Rate. We currently do not use interest rate derivative instruments to manage our exposure to interest rate fluctuations. As of December 31, 2022, a hypothetical 100 basis point increase in interest rates would have an estimated \$1.4 million impact per year on our financial position and results of operations, based on the 2020 Term Loan principal outstanding through maturity. By February 28, 2023, we paid the principal balance outstanding plus interest and prepayment fees. As of December 31, 2022, the fair value of the 2020 Term Loan was \$130.0 million. For additional information about the 2020 Term Loan, see Note 8, "Commitments and contingencies" and Note 16, "Subsequent events" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report.

Although our convertible senior notes are based on a fixed rate, changes in interest rates could impact the fair value we disclose. As of December 31, 2022, the fair market value of the convertible senior notes due 2024 and due 2028 was \$261.6 million and \$576.7 million, respectively. For additional information about the convertible senior notes, see Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report.

ITEM 8. Consolidated Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Invitae Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Invitae Corporation (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 28, 2023 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Measurement of test revenue billed to insurance carriers

Description of the Matter During the year ended December 31, 2022, the Company recognized test revenue billed to insurance carriers of \$310.3 million. As discussed in Note 2 to the consolidated financial statements, the Company often provides price concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered variable consideration. Revenue for tests billed to insurance carriers was recognized based on an estimate of the consideration to which the Company expects to be entitled at an amount for which it is probable that a reversal of cumulative revenue recognized will not occur.

Auditing the measurement of the Company's test revenue billed to insurance carriers was complex due to the significant judgment required to determine the amount of consideration to which the Company expects to be entitled. In particular, the estimate of test revenue billed to insurance carriers was based on assumptions in payer behavior such as historical payment patterns, contract provisions and government and private insurance reimbursement policies.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's revenue recognition process. For example, we tested controls over management's review of the significant assumptions and inputs used in the estimate of the amount to which the Company expects to be entitled. We also tested controls over the completeness and accuracy of the current and historical data used in the Company's revenue models.

Our audit procedures over the Company's test revenue billed to insurance carriers included, among others, assessing revenue models and testing the significant assumptions and inputs used by the Company in its analysis. We agreed a sample of transactions to the payer contract terms. We compared the significant assumptions and inputs used by management to the Company's contracted rates, government and private insurance payer collection trends, and other relevant factors. We assessed the completeness and accuracy of the historical cash collections used in the Company's revenue models. We also assessed the completeness and accuracy of adjustments to estimates of future cash collections resulting from significant contract amendments and changes in collection trends.

Impairment of long-lived assets

Description of the Matter

At December 31, 2022, the Company's property and equipment, net, intangible assets, net, and operating lease assets (collectively, long-lived assets) were \$108.7 million, \$1,012.5 million, and \$106.6 million, respectively. As discussed in Note 2 to the consolidated financial statements, long-lived assets are assessed for recoverability whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. When indicators of impairment exist, the Company compares the estimated future undiscounted net cash flows to the carrying amount of the asset group. If the carrying amount of the asset group exceeds the estimated future undiscounted cash flows, an impairment is measured based on the difference between the carrying amount of the asset group and its fair value.

Auditing the Company's recoverability test for long-lived assets was challenging due to subjective estimates and assumptions used by the Company to determine the undiscounted cash flows associated with the asset group. The estimate of undiscounted cash flows was subject to higher estimation uncertainty due to management's judgments over significant assumptions, including revenue growth and revenue multiples. Changes in these significant assumptions could have a significant effect on the undiscounted cash flows and resulting recoverability of the asset group.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness, of controls over the Company's impairment assessment for long-lived assets. For example, we tested controls over management's review of the significant inputs and assumptions in the determination of undiscounted cash flows, specifically as it relates to revenue growth and revenue multiples.

Our audit procedures over the Company's impairment assessment for long-lived assets included, among others, assessing the reasonableness of significant assumptions, specifically revenue growth and revenue multiples, and assessing the completeness and accuracy of the underlying data used by the Company in its analyses. We evaluated whether the significant assumptions were reasonable by comparing them to the past performance of the Company, current industry data and current market forecasts, and whether such assumptions were consistent with evidence obtained in other areas of the audit. We also involved our valuation specialists to assist us in evaluating the reasonableness of the Company's valuation methodologies and assumptions, including the revenue multiples as compared to industry and market data.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.

San Mateo, California

February 28, 2023

INVITAE CORPORATION

Consolidated Balance Sheets

(in thousands, except par value data)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 257,489	\$ 923,250
Marketable securities	289,611	122,121
Accounts receivable	96,148	66,227
Inventory	30,386	33,516
Prepaid expenses and other current assets	19,496	33,691
Total current assets	<u>693,130</u>	<u>1,178,805</u>
Property and equipment, net	108,723	114,714
Operating lease assets	106,563	121,169
Restricted cash	10,030	10,275
Intangible assets, net	1,012,549	1,187,994
Goodwill	—	2,283,059
Other assets	23,121	23,551
Total assets	<u>\$ 1,954,116</u>	<u>\$ 4,919,567</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 13,984	\$ 21,127
Accrued liabilities	74,388	106,453
Operating lease obligations	14,600	12,359
Finance lease obligations	5,121	4,156
Total current liabilities	<u>108,093</u>	<u>144,095</u>
Operating lease obligations, net of current portion	134,386	124,369
Finance lease obligations, net of current portion	3,780	5,683
Debt	122,333	113,391
Convertible senior notes, net	1,470,783	1,464,138
Deferred tax liability	8,130	51,696
Other long-term liabilities	4,775	37,797
Total liabilities	<u>1,852,280</u>	<u>1,941,169</u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value: 20,000 shares authorized; nil shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Common stock, \$0.0001 par value: 600,000 and 400,000 shares authorized; 245,562 and 228,116 shares issued and outstanding as of December 31, 2022 and 2021, respectively	25	23
Accumulated other comprehensive loss	(80)	(7)
Additional paid-in capital	4,931,032	4,701,230
Accumulated deficit	(4,829,141)	(1,722,848)
Total stockholders' equity	<u>101,836</u>	<u>2,978,398</u>
Total liabilities and stockholders' equity	<u>\$ 1,954,116</u>	<u>\$ 4,919,567</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Operations

(in thousands, except per share data)

	Year Ended December 31,		
	2022	2021	2020
Revenue:			
Test revenue	\$ 500,560	\$ 444,072	\$ 272,310
Other revenue	15,743	16,377	7,288
Total revenue	<u>516,303</u>	<u>460,449</u>	<u>279,598</u>
Operating expenses:			
Cost of revenue	417,256	348,669	198,275
Research and development	402,088	416,087	240,605
Selling and marketing	218,881	225,910	168,317
General and administrative	192,314	248,070	270,029
Goodwill and IPR&D impairment	2,313,047	—	—
Restructuring and other costs	140,331	—	—
Gain on sale of RUO kit assets	(47,354)	—	—
Change in fair value of contingent consideration	(1,850)	(386,646)	54,544
Total operating expenses	<u>3,634,713</u>	<u>852,090</u>	<u>931,770</u>
Loss from operations	(3,118,410)	(391,641)	(652,172)
Other income (expense), net:			
Change in fair value of acquisition-related liabilities	15,906	25,196	(37,527)
Other income, net	8,054	482	5,195
Total other income (expense), net	<u>23,960</u>	<u>25,678</u>	<u>(32,332)</u>
Interest expense	(56,747)	(49,900)	(29,766)
Net loss before taxes	(3,151,197)	(415,863)	(714,270)
Income tax benefit	44,904	36,857	112,100
Net loss	<u>\$ (3,106,293)</u>	<u>\$ (379,006)</u>	<u>\$ (602,170)</u>
Net loss per share, basic and diluted	<u>\$ (13.18)</u>	<u>\$ (1.80)</u>	<u>\$ (4.47)</u>
Shares used in computing net loss per share, basic and diluted	<u>235,676</u>	<u>210,946</u>	<u>134,587</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Comprehensive Loss

(in thousands)

	Year Ended December 31,		
	2022	2021	2020
Net loss	\$ (3,106,293)	\$ (379,006)	\$ (602,170)
Other comprehensive (loss) income:			
Unrealized (loss) income on available-for-sale marketable securities, net of tax	(73)	(8)	10
Comprehensive loss	<u>\$ (3,106,366)</u>	<u>\$ (379,014)</u>	<u>\$ (602,160)</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Stockholders' Equity

(in thousands)

	Year Ended December 31,		
	2022	2021	2020
Common stock:			
Balance, beginning of period	\$ 23	\$ 19	\$ 10
Common stock issued	2	4	9
Balance, end of period	<u>25</u>	<u>23</u>	<u>19</u>
Accumulated other comprehensive (loss) income:			
Balance, beginning of period	(7)	1	(9)
Unrealized (loss) income on available-for-sale marketable securities, net of tax	(73)	(8)	10
Balance, end of period	<u>(80)</u>	<u>(7)</u>	<u>1</u>
Additional paid-in capital:			
Balance, beginning of period	4,701,230	3,337,120	1,138,316
Common stock issued in private placement, net	—	—	263,628
Common stock issued in connection with public offering, net	9,658	434,263	263,685
Common stock issued on exercise of stock options, net	643	8,984	10,730
Common stock issued pursuant to exercises of warrants	—	1,242	974
Common stock issued pursuant to employee stock purchase plan	7,513	13,550	8,871
Common stock and equity awards issued pursuant to acquisitions	15,027	805,124	1,524,227
Warrants issued pursuant to loan agreement	—	—	27,000
Stock-based compensation expense	196,961	176,435	110,076
Reclassification of equity component of convertible senior notes	—	(75,488)	—
Reclassification of stock payable liabilities	—	—	(10,387)
Balance, end of period	<u>4,931,032</u>	<u>4,701,230</u>	<u>3,337,120</u>
Accumulated deficit:			
Balance, beginning of period	(1,722,848)	(1,360,847)	(758,677)
Cumulative effect of accounting change	—	17,005	—
Net loss	(3,106,293)	(379,006)	(602,170)
Balance, end of period	<u>(4,829,141)</u>	<u>(1,722,848)</u>	<u>(1,360,847)</u>
Total stockholders' equity	<u>\$ 101,836</u>	<u>\$ 2,978,398</u>	<u>\$ 1,976,293</u>

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2022	2021	2020
Cash flows from operating activities:			
Net loss	\$ (3,106,293)	\$ (379,006)	\$ (602,170)
Adjustments to reconcile net loss to net cash used in operating activities:			
Goodwill and IPR&D impairment	2,313,047	—	—
Impairments and losses on disposals of long-lived assets	60,507	—	—
Gain on sale of RUO kit assets	(47,354)	—	—
Depreciation and amortization	142,071	80,472	39,050
Stock-based compensation	199,304	180,075	158,747
Amortization of debt discount and issuance costs	15,587	14,226	17,204
Remeasurements of liabilities associated with business combinations	(17,756)	(411,842)	92,348
Benefit from income taxes	(44,904)	(36,857)	(112,100)
Post-combination expense for acceleration of unvested equity and deferred stock compensation	8,428	9,530	91,021
Amortization of premiums and discounts on investment securities	(1,515)	6,221	1,236
Non-cash lease expense	10,240	3,496	777
Other	1,018	1,487	(588)
Changes in operating assets and liabilities, net of businesses acquired:			
Accounts receivable	(29,921)	(16,696)	(2,814)
Inventory	3,130	(1,486)	(7,832)
Prepaid expenses and other current assets	14,195	(14,563)	(2,010)
Other assets	3,124	(3,274)	895
Accounts payable	(2,465)	(9,258)	10,186
Accrued expenses and other long-term liabilities	(13,404)	17,660	17,548
Net cash used in operating activities	(492,961)	(559,815)	(298,502)
Cash flows from investing activities:			
Purchases of marketable securities	(892,361)	(325,957)	(280,258)
Proceeds from sales of marketable securities	—	—	12,832
Proceeds from maturities of marketable securities	726,313	425,293	277,487
Acquisition of businesses, net of cash acquired	—	(247,396)	(383,753)
Proceeds from sale of RUO kit assets	44,554	—	—
Purchases of property and equipment	(53,309)	(54,720)	(22,865)
Other	—	(1,300)	(4,026)
Net cash used in investing activities	(174,803)	(204,080)	(400,583)
Cash flows from financing activities:			
Proceeds from public offerings of common stock, net	9,658	434,263	263,688
Proceeds from issuance of common stock	8,157	23,767	284,203
Proceeds from issuance of convertible senior notes, net	—	1,116,427	—
Proceeds from issuance of debt, net	—	—	129,214
Finance lease principal payments	(5,410)	(3,759)	(2,655)
Settlement of acquisition obligations	(10,647)	(4,758)	(1,457)
Net cash provided by financing activities	1,758	1,565,940	672,993
Net (decrease) increase in cash, cash equivalents and restricted cash	(666,006)	802,045	(26,092)
Cash, cash equivalents and restricted cash at beginning of period	933,525	131,480	157,572
Cash, cash equivalents and restricted cash at end of period	\$ 267,519	\$ 933,525	\$ 131,480
Supplemental cash flow information:			
Interest paid	\$ 40,504	\$ 31,400	\$ 12,130
Supplemental cash flow information of non-cash investing and financing activities:			
Consideration receivable for sale of RUO kit assets	\$ 3,000	\$ —	\$ —
Equipment acquired through finance leases	\$ 4,472	\$ 8,224	\$ 4,463
Purchases of property and equipment in accounts payable and accrued liabilities	\$ 820	\$ 13,222	\$ 1,869
Warrants issued pursuant to debt agreement	\$ —	\$ —	\$ 27,000
Common stock issued for acquisition of businesses	\$ 6,600	\$ 802,073	\$ 1,157,958
Consideration payable for acquisition of businesses	\$ —	\$ 46,649	\$ 940,829
Operating lease assets obtained in exchange for lease obligations, net	\$ 4,495	\$ 88,777	\$ 14,058

The accompanying notes are an integral part of these financial statements.

INVITAE CORPORATION

Notes to Consolidated Financial Statements

1. Organization and description of business

Invitae Corporation ("Invitae," "the Company," "we," "us," and "our") was incorporated in the State of Delaware on January 13, 2010, as Locus Development, Inc. and we changed our name to Invitae Corporation in 2012. We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, precision oncology, women's health, rare diseases and pharmacogenomics. To augment our portfolio and realize our mission, we have previously acquired multiple assets and businesses that further expanded our test menu and suite of digital health and data offerings and accelerated our entry into key genomics markets. We are building a platform to harness genetics to diagnose more patients correctly and earlier, while enabling our partners to bring therapies to market faster. Invitae operates in one segment.

Strategic realignment

On July 18, 2022, the Company initiated a strategic realignment of our operations and began implementing cost reduction programs to prioritize its core genetic testing and digital health and data platforms, which was approved by the board of directors of the Company on July 16, 2022. See Note 11, "Restructuring and other costs" for additional information regarding our strategic realignment.

2. Summary of significant accounting policies

Principles of consolidation

Our consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. We base these estimates on current facts, historical and anticipated results, trends and various other assumptions that we believe are reasonable under the circumstances, including assumptions as to future events. Actual results could differ materially from those judgments, estimates and assumptions. We evaluate our estimates on an ongoing basis.

Significant estimates and assumptions made by management include the determination of:

- revenue recognition;
- inventory adjustments;
- the fair value of assets and liabilities associated with business combinations;
- the impairment assessment of goodwill and intangible assets;
- the recoverability of long-lived assets;
- our incremental borrowing rates used to calculate our lease balances;
- stock-based compensation expense and the fair value of awards and warrants issued; and
- income tax uncertainties.

Concentrations of credit risk and other risks and uncertainties

Financial instruments that potentially subject us to a concentration of credit risk consist of cash, cash equivalents, restricted cash, marketable securities and accounts receivable. Our cash and cash equivalents are held by financial institutions in the United States. Such deposits may exceed federally insured limits.

Significant customers are those that represent 10% or more of our total revenue for each year presented in the consolidated statements of operations. Our revenue and accounts receivable from significant customers as a percentage of our total revenue and total accounts receivable was as follows:

	Revenue			Accounts receivable	
	Year Ended December 31,			December 31,	
	2022	2021	2020	2022	2021
Medicare	14 %	15 %	19 %	16 %	*

* less than 10%

Cash, cash equivalents, and restricted cash

We consider all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds, U.S. Treasury notes and government agency securities.

Restricted cash consists primarily of money market funds that secure irrevocable standby letters of credit that serve as collateral for security deposits for our facility leases.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows (in thousands):

	December 31,	
	2022	2021
Cash and cash equivalents	\$ 257,489	\$ 923,250
Restricted cash	10,030	10,275
Total cash, cash equivalents and restricted cash	\$ 267,519	\$ 933,525

Marketable securities

All marketable securities have been classified as “available-for-sale” and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its marketable debt securities at the time of purchase and reevaluates such designation at each balance sheet date. Short-term marketable securities have maturities one year or less at the balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive loss. Realized gains and losses and impairments, if any, on available-for-sale securities are included in other income (expense), net. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in other income (expense), net.

For marketable securities in an unrealized loss position, we assess our intent to sell, or whether it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. If either of these criteria are met, the security’s amortized cost basis is written down to fair value through other income (expense), net.

Accounts receivable

We receive payment from patients, biopharmaceutical partners, third-party payers and other business-to-business customers. See Note 3, "Revenue, accounts receivable and deferred revenue" for further information.

Allowances for losses on certain financial assets

We assess our accounts receivables for expected credit losses at each reporting period by disaggregating by payer type and further by portfolios of customers with similar characteristics, such as customer type and geographic location. We then review each portfolio for expected credit losses based on historical payment trends as well as forward looking data and current economic trends. If a credit loss is determined, we record a reduction to our accounts receivable balance with a corresponding general and administrative expense.

We review available-for-sale debt securities in an unrealized loss positions at each balance sheet date and assess whether such unrealized loss positions are credit-related. Our expected loss allowance methodology for these securities is developed by reviewing the extent of the unrealized loss, the issuers’ credit ratings and any changes in those ratings, as well as reviewing current and future economic market conditions and the issuers’ current status and financial condition. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income (expense), net. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive loss.

Deferred revenue

We record a contract liability when cash payments are received or due in advance of our performance related to one or more performance obligations. See Note 3, "Revenue, accounts receivable and deferred revenue" for further information.

Inventory

Our inventory consists of raw materials, work in progress, and finished goods, which are stated at the lower of cost or net realizable value on a first-in, first-out basis. We periodically analyze our inventory levels and expiration dates, and write down inventory that has become obsolete, inventory that has a cost basis in excess of its net realizable value, and inventory in excess of expected sales requirements as cost of revenue. We record an allowance for obsolete inventory using an estimate based on historical trends and evaluation of near-term expirations.

Business combinations

We apply ASC 805, *Business Combinations*, which requires recognition of assets acquired, liabilities assumed, and contingent consideration at their fair value on the acquisition date with subsequent changes recognized in earnings; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination and expensed as incurred; requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset until completion or abandonment; and requires that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of provision for taxes.

We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. We base the estimated fair value of identifiable intangible assets acquired in a business combination on third-party valuations that use information and assumptions provided by our management, which consider our estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, estimated cost savings, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under ASC 480, *Distinguishing Liabilities from Equity*, we recognize a liability equal to the fair value of the contingent payments we expect to make as of the acquisition date. We remeasure this liability each reporting period and record changes in the fair value in change in fair value of contingent consideration in our consolidated statements of operations.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in our operating results from the date of acquisition.

Asset acquisitions

In circumstances where substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the asset is not considered a business and we account for the transaction as an asset acquisition. We recognize the assets acquired based on their relative fair value, which generally includes the transaction costs of the asset acquisition, and no gain or loss is recognized unless the fair value of noncash assets given as consideration differs from the assets' carrying amounts. The form of consideration transferred may be cash, liabilities incurred, or equity interests issued.

Intangible assets

Amortizable intangible assets include trade names, non-compete agreements, patent licensing agreements, favorable leases, developed technology, customer relationships, and rights to develop new technology acquired as part of business combinations. Customer relationships acquired through our business combinations in 2017 are amortized on an accelerated basis, utilizing free cash flows, over periods ranging from five to 11 years. All other intangible assets subject to amortization are amortized using the straight-line method over their estimated useful lives

ranging from five to 12 years. All intangible assets subject to amortization are reviewed for impairment in accordance with ASC 360, *Property, Plant and Equipment*.

Goodwill

In accordance with ASC 350, *Intangibles-Goodwill and Other*, our goodwill is not amortized but is tested for impairment on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. Under ASC 350, we perform annual impairment reviews of our goodwill balance during the fourth fiscal quarter or more frequently if business factors indicate. In testing for impairment, we compare the fair value of our reporting unit to its carrying value including the goodwill of that unit. If the carrying value, including goodwill, exceeds the reporting unit’s fair value, we will recognize an impairment loss for the amount by which the carrying amount exceeds the reporting unit’s fair value. The loss recognized cannot exceed the total amount of goodwill allocated to that reporting unit.

In-process research and development

Intangible assets related to IPR&D are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. During this period, the assets will not be amortized but will be tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts.

During the fourth quarter and if business factors indicate more frequently, we perform an assessment of the qualitative factors affecting the fair value of our IPR&D projects. If the fair value exceeds the carrying value, there is no impairment. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of an asset to its carrying value, without consideration of any recoverability test.

Leases

Under ASC 842, *Leases*, we determine if an arrangement is a lease at inception. Operating leases are included in operating lease assets and operating lease obligations in our consolidated balance sheets. Finance leases are included in other assets and finance lease obligations in our consolidated balance sheets.

Lease assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at commencement based on the present value of lease payments over the lease term. We generally use our incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments. The operating lease asset also includes any lease payments made and is adjusted for lease incentives. Our lease terms may include options to extend or terminate the lease which are recognized when it is reasonably certain that we will exercise that option. Leases with terms of 12 months or less are not recorded on our balance sheet. Lease expense is recognized on a straight-line basis over the lease terms, or in some cases, the useful life of the underlying asset. We account for the lease and non-lease components of our operating right-of-use assets as a single lease component.

Property and equipment, net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and seven years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

The estimated useful lives of property and equipment are as follows:

Furniture and fixtures	7 years
Automobiles	7 years
Manufacturing and Laboratory equipment	5 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	Shorter of lease term or estimated useful life

Long-lived assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows or other appropriate measures of fair value.

During the year ended December 31, 2022, we recognized losses on disposal of property and equipment of \$19.1 million, which are recorded in restructuring and other costs in the consolidated statements of operations. See Note 5, "Goodwill and intangible assets" under the heading "Impairment assessment" and Note 6, "Balance sheet components" under the heading "Property and equipment, net" for additional information. We did not incur any losses on disposal of property and equipment during the years ended December 31, 2021 and 2020, respectively.

Fair value of financial instruments

Our financial instruments consist principally of cash and cash equivalents, marketable securities, accounts payable, accrued liabilities, finance lease liabilities, and liabilities associated with business combinations. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued and other current liabilities approximate their current fair value due to the relatively short-term nature of these accounts. Based on borrowing rates available to us, the carrying value of our finance lease liabilities approximates their fair values. Liabilities associated with business combinations are recorded at their estimated fair value.

Revenue recognition

We recognize revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers. We utilize the following practical expedients and exemptions:

- Costs to obtain or fulfill a contract are expensed when incurred because the amortization period would have been one year or less, and
- No adjustments to promised consideration were made for financing as we expect, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

Test revenue

Test revenue is comprised of testing services and sales of distributed precision oncology products.

The majority of our test revenue is generated from genetic testing, in addition to somatic testing for therapy selection and personalized cancer monitoring. These testing services provide analysis and associated interpretation of the sequencing of parts of the genome. Test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with insurance companies and institution customers that include pricing provisions under which such tests are billed. Billing terms are generally net 30 to 60 days.

While the transaction price of diagnostic tests is originally established either via contract or pursuant to our standard list price, we often provide concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which we will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur. Making these estimates requires significant judgments based upon such factors as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. These judgments are reviewed each reporting period and updated as necessary.

We look to transfer of control in assessing timing of recognition of revenue in connection with each performance obligation. In general, revenue in connection with the service portion of our diagnostic tests is recognized upon delivery of the underlying clinical report or when the report is made available on our web portal. Outstanding performance obligations pertaining to orders received but for which the underlying report has not been issued are generally satisfied within a 30-day period.

We also generated test revenue through the sale of our distributed precision oncology products, which is comprised primarily of sales of our RUO kit and IVD product offerings for therapy selection. We recognized revenue on these sales once shipment had occurred. Product sales were recorded net of discounts and other deductions. Billing terms were generally net 30 days. As part of the strategic realignment, we exited these product offerings in fiscal year 2022. See Note 4, "Business combinations and dispositions" for additional information on the disposition of

the RUO kit assets. See Note 5, "Goodwill and intangible assets" for additional information on the exit of the IVD product offering.

Shipping and handling fees billed to customers are recorded as revenue in the consolidated statements of operations. The associated shipping and handling costs are recorded as cost of revenue.

Other revenue

Other revenue is primarily generated from collaboration agreements and genome network contracts as well as pharma development services provided to biopharmaceutical companies related to companion diagnostic development.

We enter into collaboration and genome network contracts. Collaboration agreements provide customers with diagnostic testing and related data aggregation reporting services that are provided over the contract term. Collaboration revenue is recognized as the data and reporting services are delivered to the customer. Genome network offerings consist of subscription services related to a proprietary software platform designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis and treatment of hereditary disease. Such services are recognized on a straight-line basis over the subscription periods. Amounts due under collaboration and genome network agreements are typically billable on net 30-day terms.

Contracts for companion diagnostic development consisted primarily of milestone-based payments along with annual fees and marked-up pass-through costs. The arrangements were treated as short-term contracts for revenue recognition purposes because they allow termination of the agreements by the customers with 30 to 120 days' written notice without a termination penalty. Upon termination, customers were required to pay for the proportion of services provided under milestones that were in progress. We recognized revenue in an amount that reflected the consideration which we expect to receive in exchange for those goods or services. We recognized revenue as services are provided based on the progress made toward achieving the performance obligation, utilizing input methods, including labor hours expended and tests processed, that measure our progress toward the achievement of the milestone.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering our products and services and includes expenses for materials and supplies, personnel-related costs, freight, costs for lab services and clinical trial support, equipment and infrastructure expenses and allocated overhead including rent, information technology costs, equipment depreciation, amortization of acquired intangibles, and utilities.

License Agreements

We have entered and may continue to enter into license agreements to access and utilize certain technology. We evaluate if the license agreement results in the acquisition of an asset or a business and then determine if the acquired asset has the ability to generate revenues or is subject to regulatory approval. When regulatory approval is not required, we record the license as an asset and amortize it over the estimated economic life. When regulatory approval is required, we record the amount paid as a research and development expense.

Advertising

Advertising expenses are expensed as incurred. We incurred advertising expenses of \$5.9 million, \$20.2 million and \$11.4 million during the years ended December 31, 2022, 2021 and 2020, respectively.

Stock-based compensation

We measure stock-based payment awards made to employees and directors based on the estimated fair values of the awards and recognize the compensation expense over the requisite service period. We use the Black-Scholes option-pricing model to estimate the fair value of stock option awards and ESPP purchases. The fair value of RSU awards with time-based vesting terms is based on the grant date share price. We grant PRSU awards to certain employees, which vest upon the achievement of certain performance conditions subject to the employees' continued service relationship with us. The probability of vesting is assessed at each reporting period and compensation cost is adjusted based on this probability assessment. We recognize such compensation expense on an accelerated vesting method.

Stock-based compensation expense for awards without a performance condition is recognized using the straight-line method. Stock-based compensation expense is based on the value of the portion of stock-based payment

awards that is ultimately expected to vest. As such, our stock-based compensation is reduced for estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

We account for stock issued in connection with business combinations based on the fair value on the date of issuance.

Restructuring and other costs

Restructuring and other costs are comprised of employee severance and benefits, asset impairments and losses on asset disposals, and other costs primarily related to implementing our strategic realignment. Employee separation costs are comprised of severance, other termination benefit costs, and stock-based compensation expense for the acceleration of stock awards related to workforce reductions. We recognize costs and liabilities associated with exit and disposal activities in accordance with ASC 420, *Exit and Disposal Cost Obligations*, and other costs and liabilities associated with postemployment nonretirement benefits in accordance with ASC 712, *Postemployment Nonretirement Benefits*. Liabilities are based on the estimate of fair value in the period the liabilities are incurred, with subsequent changes to the liability recognized as adjustments in the period of change. We recognize losses on asset disposals in accordance with ASC 360, *Impairment or Disposal of Long-Lived Assets*. Restructuring and other costs are recognized as an operating expense within the consolidated statements of operations and the related liabilities are recorded within accrued liabilities in the consolidated balance sheets.

Income taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Significant judgment is required in determining the net valuation allowance which includes our evaluation of all available evidence including past operating results, estimates on future taxable income and acquisition-related tax assets and liabilities.

We historically established a full valuation allowance against our deferred tax assets due to the uncertainty surrounding realization of such assets.

Comprehensive loss

Comprehensive loss is composed of two components: net loss and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' equity, but are excluded from net loss. Our other comprehensive income (loss) consists of unrealized gains or losses on investments in available-for-sale securities.

Net loss per share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury stock method. Potentially dilutive securities, consisting of preferred stock, options to purchase common stock, common stock warrants, shares of common stock pursuant to ESPP, common stock issuable in connection with our convertible senior notes, RSUs and PRSUs, are considered to be common stock equivalents and were excluded from the calculation of diluted net loss per share because their effect would be antidilutive for all periods presented.

Recent accounting pronouncements

We evaluate all Accounting Standards Updates ("ASUs") issued by the FASB for consideration of their applicability. ASUs not included in the disclosures in this report were assessed and determined to be either not applicable or are not expected to have a material impact on our consolidated financial statements.

Recently issued accounting pronouncements not yet adopted

In October 2021, the FASB issued ASU 2021-08, *Business Combinations ("Topic 805"): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*. The amendments of this ASU require entities to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC 606, *Revenue from Contracts with Customers*. At the acquisition date, an acquirer should account for the related revenue contracts in accordance with ASC 606 as if it had originated the contracts. The amendments improve

comparability after the business combination by providing consistent recognition and measurement guidance for revenue contracts with customers acquired in a business combination and revenue contracts with customers not acquired in a business combination. The amendments in this update are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, and should be applied prospectively to all business combinations occurring after the date of adoption. Early adoption is permitted. We are currently evaluating the impact this guidance will have on our consolidated financial statements.

Recently adopted accounting pronouncements

In August 2020, the FASB issued ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for certain convertible instruments, amends the guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. This new standard is effective for our interim and annual periods beginning January 1, 2022, with early adoption permitted. We elected to adopt the amendments on a modified retrospective basis effective January 1, 2021, which required a cumulative-effect adjustment to retained earnings. The cumulative-effect adjustment resulted in a decrease in accumulated deficit of \$17.0 million related to the reversal of the equity component and associated issuance costs as well as adjustment of the related amortization costs of our convertible senior notes due 2024. Reporting periods beginning on or after January 1, 2021 are presented under this new guidance while prior periods have not been adjusted and continue to be reported in accordance with our historic accounting under U.S. GAAP. See Note 8, "Commitments and contingencies" for additional information about our convertible senior notes.

3. Revenue, accounts receivable and deferred revenue

During the year ended December 31, 2022, the Company changed its presentation of disaggregated revenue from revenue by services and products to clinical category of our product offerings to better align with our operations. The change had no impact on the timing of revenue recognition and had no effect on our reported results of operations. Presentation of disaggregated revenue by services and products in prior periods have been modified to conform to the current period presentation.

Test revenue is generated from sales of diagnostic tests and precision oncology products to two groups of customers: patients, consideration for which may be paid directly by the patients or by the patients' insurance carriers, and institutions (e.g., hospitals, clinics, medical centers and biopharmaceutical partners). Amounts billed and collected, and the timing of collections, vary based on the type of customer and the corresponding payer, including the patients' insurance carriers that are paying on behalf of the customer. Data and service revenue consists principally of revenue recognized for the performance of activities as outlined in biopharmaceutical development contracts and other collaboration and genome network agreements.

The following tables present revenue disaggregated by customer and product offering by disease category (in thousands):

	Patient			Year Ended December 31, 2022
	Insurance	Direct	Institution	
Product:				
Oncology	\$ 208,239	\$ 10,327	\$ 89,922	\$ 308,488
Women's health	70,571	18,082	7,127	95,780
Rare diseases	31,527	10,044	24,462	66,033
Data/services	—	—	46,002	46,002
Total revenue	\$ 310,337	\$ 38,453	\$ 167,513	\$ 516,303

	Patient			Year Ended December 31, 2021
	Insurance	Direct	Institution	
Product:				
Oncology	\$ 200,456	\$ 11,341	\$ 70,439	\$ 282,236
Women's health	52,759	21,316	8,696	82,771
Rare diseases	23,701	9,011	24,504	57,216
Data/services	—	—	38,226	38,226
Total revenue	\$ 276,916	\$ 41,668	\$ 141,865	\$ 460,615

Product:	Patient			Year Ended December 31, 2020
	Insurance	Direct	Institution	
Oncology	\$ 142,552	\$ 6,479	\$ 25,868	\$ 174
Women's health	25,050	12,684	6,404	44
Rare diseases	13,424	4,809	16,320	34
Data/services	—	—	26,008	26
Total revenue	<u>\$ 181,026</u>	<u>\$ 23,972</u>	<u>\$ 74,600</u>	<u>\$ 279</u>

We recognize revenue related to billings based on estimates of the amount that will ultimately be realized. Cash collections for certain tests delivered may differ from rates originally estimated. In subsequent periods, we update our estimate of the amounts recognized for previously delivered tests resulting in the following increases to revenue and decreases to our net loss from operations and basic and diluted net loss per share (in millions, except per share data):

	Year Ended December 31,		
	2022	2021	2020
Revenue	\$ 2.8	\$ 13.5	\$ 4.4
Loss from operations	\$ (2.8)	\$ (13.5)	\$ (4.4)
Net loss per share, basic and diluted	\$ (0.01)	\$ (0.06)	\$ (0.03)

The increase in revenue from previously delivered tests for the years ended December 31, 2022, 2021 and 2020 was primarily due to higher average revenue per test across all test categories when compared to initial estimates.

Impact of COVID-19

We expect the COVID-19 pandemic may continue to impact our business. We have reviewed and adjusted, when necessary, for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

In March 2020, the CARES Act was signed into law as a stimulus bill intended to bolster the economy, among other things, and provide assistance to qualifying businesses and individuals. The CARES Act included an infusion of funds into the healthcare system. In April 2020, we received \$3.8 million as a part of this initiative, and in January 2021, we received an additional \$2.3 million. These payments were recognized as other income (expense), net in our consolidated statements of operations during the periods received. At this time, we are not certain of the availability, extent or impact of any future relief provided under the CARES Act.

Accounts receivable

The majority of our accounts receivable represents amounts billed to customers for test and data and service activities, and the estimated amounts to be collected from patients' insurance carriers for test services.

We record a contract asset for services delivered under certain biopharmaceutical contracts, which are unbilled as of the end of the period. The contract receivable was \$1.3 million and \$4.3 million as of December 31, 2022 and 2021, respectively, and was included in prepaid expenses and other current assets in the consolidated balance sheets.

Deferred revenue

We record a contract liability when cash payments are received or due in advance of our performance related to one or more performance obligations. The deferred revenue balance primarily consists of advanced billings for biopharmaceutical development services, including billings at the initiation of performance-based milestones, and recognized as revenue in the applicable future period when the revenue is earned. Also included are prepayments related to our consumer direct channel. We recognized revenue of \$4.7 million and \$2.9 million from deferred revenue for the years ended December 31, 2022 and 2021, respectively. The current contract liability was \$4.8 million and \$9.4 million as of December 31, 2022 and 2021, respectively, which was included in accrued liabilities in the consolidated balance sheets. The long-term contract liability was \$0.1 million and \$0.7 million as of December 31, 2022 and 2021, respectively, and was included in other long-term liabilities in the consolidated balance sheets.

Refund liability

As part of our strategic realignment, we terminated early or changed the scope of several companion diagnostic development contracts with milestones in progress. Upon termination, we recorded a refund liability related to the remaining outstanding performance-based milestones. The refund liability was \$4.7 million and \$1.2 million as of December 31, 2022 and 2021, respectively, which was included in accrued liabilities in the consolidated balance sheets.

Performance obligations

Test and other revenue are generally recognized upon completion of our performance obligation when or as control of the promised good or service is transferred to the customer, typically a test report or upon shipment of our precision oncology products or other contractually defined milestone(s). The Company has applied the practical expedient in relation to information about our remaining performance obligations, as we have a right to consideration from a customer in an amount that corresponds directly with the value to the customer of the Company's performance completed to date. Most remaining performance obligations are primarily related to PCM services included in test revenue in our consolidated statement of operations and are generally satisfied over one to six months.

4. Business combinations and dispositions

Genelex and YouScript

In April 2020, we acquired 100% of the equity interest of Genelex and YouScript to bring pharmacogenetic testing and integrated clinical decision support to Invitae. We acquired Genelex for approximately \$13.2 million, primarily in shares of our common stock. Of the stock purchase price consideration issued, approximately 0.1 million shares were subject to a hold-back to satisfy indemnification obligations that may arise. We acquired YouScript for approximately \$52.7 million, including cash consideration of \$24.5 million and the remainder in shares of our common stock. Of the purchase price consideration for YouScript, approximately \$1.4 million and 0.5 million shares of our common stock were subject to a hold-back to satisfy indemnification obligations that may arise.

As of the acquisition date, we recorded stock payable liabilities of \$6.2 million to represent the hold-back obligation to issue shares subject to indemnification claims that may arise. In April 2021, the amounts held back to satisfy indemnification obligations for Genelex were released in full to the former shareholders. As of December 31, 2021, the value of these liabilities were \$3.5 million related to YouScript and were included in other long-term liabilities in the consolidated balance sheets, with the \$15.4 million change in fair value year over year recorded in other income (expense), net in the consolidated statement of operations. In April 2022, the amounts held back to satisfy indemnification obligations for YouScript were released in full to the former shareholders.

We may be required to pay contingent consideration in the form of additional shares of our common stock in connection with the acquisition of Genelex if, within a specified period following the closing, we achieve a certain product milestone, in which case we would issue shares of our common stock with a value equal to a portion of the gross revenues actually received by us for a pharmacogenetic product reimbursed through certain payers during an earn-out period of up to four years. As of the acquisition date, the fair value of this contingent consideration was \$2.0 million. This fair value measurement is based on significant inputs not observable in the market and, therefore, represents a Level 3 measurement. The material factors that may impact the fair value of the contingent consideration, and therefore, this liability, are the probabilities and timing of achieving the related milestone, the estimated revenues achieved for a pharmacogenetic product and the discount rate used to estimate the fair value. Significant changes in any of the probabilities of success would result in a significant change in the fair value, which is estimated at each reporting date. As of December 31, 2022 and 2021, the fair value of this contingent consideration was immaterial and \$1.9 million, respectively.

ArcherDX

In October 2020, we acquired ArcherDX, a genomics analysis company. Under the terms of the agreement, we acquired ArcherDX for upfront consideration consisting of 30.0 million shares of our common stock and \$325.0 million in cash, plus up to an additional 27.0 million shares of our common stock payable in connection with the achievement of certain milestones. During the three months ended March 31, 2021, Invitae and the sellers of ArcherDX reached an agreement to reduce the purchase price by \$1.2 million based on the final acquired net working capital. This adjustment was recorded during the three months ended March 31, 2021 and reduced the contingent consideration liability and goodwill by approximately \$1.2 million.

We were required to pay contingent consideration based on achievement of post-closing development and revenue milestones. The material factors that may impact the fair value of the contingent consideration, and therefore the liability, are (i) the estimated number of shares to be issued, (ii) the volatility of our common stock, (iii) the

probabilities of achievement of milestones within the timeframes prescribed in the acquisition agreement and (iv) discount rates, all of which are Level 3 inputs not supported by market activity with the exception of the volatility of our common stock. Significant changes in any of these inputs may result in a significant change in fair value, which is estimated at each reporting date. Of the five milestones, one milestone was achieved in November 2020, which resulted in the issuance of 5.0 million shares of our common stock and a cash payment of \$1.9 million, and three milestones were achieved or deemed to be achieved during the three months ended June 30, 2021, which resulted in the issuance of 13.8 million shares of our common stock and a cash payment of \$3.3 million in July 2021. The remaining milestone is based upon receiving FDA clearance or approval of a therapy selection IVD, which per the terms of the acquisition agreement, must be completed by March 31, 2022, subject to certain extensions (the "ArcherDX Final Milestone"). With respect to the ArcherDX Final Milestone, the liability was reduced to zero as of June 30, 2021 from \$262.5 million as of March 31, 2021 and \$287.7 million as of December 31, 2020, with the offsetting change recorded as changes in fair value of contingent consideration in our consolidated statements of operations. The removal of the liability balance and the associated change in fair value of contingent consideration was a result of our reassessment of the steps necessary to achieve clearance or approval based on FDA feedback received principally in the three months ended June 30, 2021. In April 2022, an agreement was entered into with the previous ArcherDX stockholders to extend the date for achievement of the ArcherDX Final Milestone to March 31, 2023. We currently do not believe that this milestone will be achieved within this timeframe. As such, no liability was recorded as of December 31, 2022.

In connection with the acquisition, we granted awards of common stock to new employees who joined Invitae in connection with our acquisition of ArcherDX that vested upon the achievement of the contingent consideration milestones discussed above and were subject to the employees' continued service with us, unless terminated without cause in which case vesting was only dependent on milestone achievement. As the number of shares that were expected to be issued are fixed, the awards are equity-classified. During the year ended December 31, 2022, we recorded stock-based compensation expense of zero related to the ArcherDX milestones. During the year ended December 31, 2021, we recorded a net \$41.8 million in stock-based compensation expense related to the ArcherDX milestones, which includes \$38.5 million related to milestones achieved in prior periods, \$33.0 million due to an accounting modification of certain awards whereby the employees' continued substantive services were no longer required, offset by a reversal of \$29.7 million recognized in prior periods related to the determination that the ArcherDX Final Milestone would not be achieved within the specified timeframe prescribed in the acquisition agreement.

Disposition of RUO kit assets

In December 2022, we completed a transaction with IDT for net cash proceeds of \$44.5 million. The transaction value includes total cash consideration of \$48.1 million, subject to certain adjustments, including \$3.0 million of up front consideration subject to a hold-back to satisfy indemnification obligations that may arise. The disposition is part of our strategic realignment whereby we sold to IDT select assets and liabilities related to the RUO kit product offering, which represents the RUO distributed target enrichment kit and data analysis platform of ArcherDX. The transaction also includes certain licensed rights to our AMP technology. Assets sold primarily include property and equipment and inventory with a carrying value of zero. After adjustments, the sale resulted in a gain of approximately \$47.4 million during the three months ended December 31, 2022, and is included in gain on sale of RUO kit assets in our consolidated statements of operations. As of December 31, 2022, the \$3.0 million of up front consideration subject to a hold-back is included within other assets in our consolidated balance sheets.

Additionally, we entered into an agreement to sublease office space in Boulder, Colorado. See Note 8, "Commitments and contingencies" under the heading "Leases" for additional information regarding the sublease.

One Codex

In February 2021, we acquired 100% of the equity interest of One Codex, a company developing and commercializing products and services relating to microbiome sequencing, analysis and reporting, for upfront consideration consisting of \$17.3 million in cash and 1.4 million shares of our common stock, of which approximately 0.2 million shares were subject to a hold-back to satisfy indemnification obligations that may have arisen following the closing. These shares subject to a hold-back were issued to a third-party at the closing date to hold in escrow until the escrow period is complete, and as such were classified as equity. In February 2022, the amounts held back to satisfy indemnification obligations were released in full to the former stockholders.

Disposition of One Codex intangible assets

In September 2022, we sold our equity interest in One Codex and certain related assets for an immaterial amount of cash proceeds, as part of our strategic realignment. The disposition of One Codex was considered to be an

asset sale as substantially all of the fair value was concentrated in the developed technology and certain customer relationships. The carrying value of assets sold include developed technology of \$19.4 million and customer relationships of \$0.4 million. The sale resulted in a loss of approximately \$19.8 million during the three months ended September 30, 2022, which is included in restructuring and other costs in our consolidated statements of operations. See Note 5, "Goodwill and intangible assets" and Note 11, "Restructuring and other costs" for additional information.

Genosity

In April 2021, we acquired 100% of the fully diluted equity of Genosity, a company providing genomic laboratory services, for approximately \$196.0 million, consisting of approximately \$120.0 million in cash and 1.9 million shares of our common stock. In connection with this transaction, we granted RSUs having a value of up to \$5.0 million to certain continuing employees and recognized \$1.7 million and \$0.8 million in stock-based compensation expense for the years ended December 31, 2022 and 2021, respectively.

Pursuant to the terms of the acquisition, we agreed to provide additional shares in the event that our common stock share price decreased after the acquisition, but prior to filing a resale registration statement. At the time of the acquisition, we estimated this provision to be \$7.0 million. On filing the resale registration statement during the period ended June 30, 2021, the fair value was \$3.2 million and the difference of \$3.8 million was recorded in general and administrative expense in the consolidated statements of operations.

Ciitizen

In September 2021, we acquired 100% of the equity of Ciitizen, a patient-centric health technology company, for approximately \$308.3 million, consisting of approximately \$87.4 million in cash and 6.3 million shares of our common stock, of which approximately \$10.4 million in cash and 0.8 million shares are subject to a hold-back to satisfy indemnification obligations that may arise following the closing. As of December 31, 2022 and 2021, the value of the stock payable liability was \$0.4 million and \$12.1 million, respectively, which was recorded in other long-term liabilities in the consolidated balance sheets with the fair value change of \$9.7 million and \$10.6 million for the years ended December 31, 2022 and 2021, respectively, recorded as income in other income (expense), net in the consolidated statements of operations. In September 2022, the amounts held back to satisfy indemnification obligations were partially released to the former stockholders. The remaining amounts held back to satisfy indemnification obligations are expected to be released in September 2023. In connection with this transaction, we granted RSUs having a value of up to \$246.9 million to certain continuing employees. During the years ended December 31, 2022 and 2021, we recorded stock-based compensation expense of \$87.2 million and \$24.4 million, respectively, primarily in research and development expense. Additionally, during the year ended December 31, 2022, we recorded \$29.0 million of stock-based compensation expense related to the acceleration of RSUs for employees who were terminated as part of our strategic realignment, which is included in restructuring and other costs in the consolidated statements of operations. See Note 10, "Stock incentive plans" for additional information.

5. Goodwill and intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows (in thousands):

Balance as of December 31, 2021	\$ 2,283,059
Impairment	(2,283,059)
Balance as of December 31, 2022	<u>\$ —</u>

Intangible assets

The following table presents details of our acquired intangible assets as of December 31, 2022 (in thousands):

December 31, 2022						
	Cost	Accumulated Amortization	Asset Disposals	Net	Weighted-Average Useful Life (In Years)	Weighted-Average Estimated Remaining Useful Life (In Years)
Customer relationships	\$ 41,515	\$ (17,675)	\$ (359)	\$ 23,481	10.8	6.8
Developed technology	1,174,506	(183,133)	(19,426)	971,947	10.8	9.3
Non-compete agreement	286	(286)	—	—	—	—
Trade name	21,085	(3,964)	—	17,121	12.0	9.8
Patent assets and licenses	495	(156)	(339)	—	—	—
Right to develop new technology	19,359	(2,474)	(16,885)	—	—	—
	<u>\$ 1,257,246</u>	<u>\$ (207,688)</u>	<u>\$ (37,009)</u>	<u>\$ 1,012,549</u>	10.8	9.2

The following table presents details of our acquired intangible assets as of December 31, 2021 (in thousands):

December 31, 2021					
	Cost	Accumulated Amortization	Net	Weighted-Average Useful Life (In Years)	Weighted-Average Estimated Remaining Useful Life (in Years)
Customer relationships	\$ 41,515	\$ (13,096)	\$ 28,419	10.8	7.8
Developed technology	662,106	(81,902)	580,204	10.2	9.1
Non-compete agreement	286	(286)	—	—	—
Trade name	21,085	(2,207)	18,878	12.0	10.8
Patent assets and licenses	495	(136)	359	15.0	10.9
Right to develop new technology	19,359	(1,613)	17,746	15.0	13.8
In-process research and development	542,388	—	542,388	n/a	n/a
	<u>\$ 1,287,234</u>	<u>\$ (99,240)</u>	<u>\$ 1,187,994</u>	10.4	9.2

Acquisition-related intangibles included in the above tables are generally finite-lived, other than in-process research and development, which has an indefinite life, and are carried at cost less accumulated amortization. Customer relationships related to our 2017 business combinations are being amortized on an accelerated basis in proportion to estimated cash flows. All other finite-lived acquisition-related intangibles are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized. During the year ended December 31, 2022, the IVD and PCM products were fully developed resulting in the reclassification of \$512.4 million of the related IPR&D intangibles to developed technology intangibles, which are finite-lived and amortizable. Amortization expense was \$108.4 million, \$58.8 million, and \$26.6 million for the years ended December 31, 2022, 2021 and 2020, respectively. Amortization expense is recorded in cost of revenue, research and development, and selling and marketing expense.

In August 2022, in conjunction with the strategic realignment, management decided to exit the IVD product offering and we wrote-off the related intangible asset of \$16.9 million. Management also decided to exit the in-vitro fertilization product offering, and as a result we wrote-off the associated intangible asset of \$0.3 million. These charges are included in restructuring and other costs in the consolidated statements of operations. See Note 11, "Restructuring and other costs" for additional information.

See Note 4, "Business combinations and dispositions" for additional information on the sale of our interest in One Codex and the related disposition of developed technology and customer relationships during the three months ended September 30, 2022.

The following table summarizes our estimated future amortization expense of intangible assets with finite lives as of December 31, 2022 (in thousands):

2023	\$ 114,440
2024	114,162
2025	112,408
2026	112,374
2027	111,708
Thereafter	447,457
Total estimated future amortization expense	<u>\$ 1,012,549</u>

In December 2021, we acquired 100% of the equity interest of Stratify, a cancer risk stratification company, for \$29.0 million consisting of 1.0 million shares of common stock, \$4.2 million in assumed liabilities, and \$8.0 million in cash. We accounted for this transaction as an asset acquisition, as substantially all of the fair value is concentrated in the developed technology acquired. As goodwill is not recorded under an asset acquisition, an \$8.7 million deferred tax liability arising from book/tax basis differences increased the value of the assets acquired above the purchase price. As a result, the fair value of the developed technology is \$37.5 million, which will be amortized over eight years to cost of revenue. The remaining purchase price of \$0.2 million is the fair value of cash and cash equivalents.

In July 2021, we acquired 100% of the equity interest of Medneon, a digital health artificial intelligence company, for \$34.1 million consisting of 0.4 million shares of common stock, \$4.9 million in assumed liabilities, and \$12.9 million in cash. We accounted for this transaction as an asset acquisition, as substantially all of the fair value is concentrated in the developed technology acquired. The fair value of the developed technology is \$33.9 million, which will be amortized over eight years to cost of revenue. The remaining purchase price of \$0.2 million is the fair value of cash and cash equivalents.

Impairment assessment

Goodwill and indefinite-lived intangible assets are assessed for impairment on an annual basis and whenever events and circumstances indicate that these assets may be impaired. We evaluate the fair value of long-lived assets, which include property and equipment and finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amounts of the asset may not be fully recoverable. In testing for goodwill impairment, we have the option of first performing a qualitative assessment to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If we elect to bypass the qualitative assessment, or if a qualitative assessment indicates it is more likely than not that the carrying value exceeds its fair value, we perform a quantitative goodwill impairment test to compare to the fair value of our reporting unit to its carrying value, including goodwill. If the carrying value, including goodwill, exceeds the reporting unit's fair value, we will recognize an impairment loss for the amount by which the carrying amount exceeds the reporting unit's fair value. Factors that may indicate potential impairment and trigger an impairment test include, but are not limited to, current economic, market and geopolitical conditions, including a significant, sustained decline in our stock price and market capitalization compared to the net book value, an adverse change in legal factors, business climate or operational performance of the business, or significant changes in the ability of a particular asset (or group of assets) to generate positive cash flows for our strategic business objectives.

During the three months ended June 30, 2022, as a result of the significant, sustained decline in our stock price and related market capitalization and lower than expected financial performance, we performed an impairment assessment of goodwill, IPR&D intangible assets, and long-lived assets, including definite-lived intangibles.

For our goodwill, we measured the fair value of the reporting unit utilizing the discounted cash flow method under the income approach. This approach relies on significant unobservable inputs including, but not limited to, management's forecasts of projected revenue associated with future cash flows, discount rates, and control premium. Based on this analysis, we recognized a non-cash, pre-tax goodwill impairment charge of \$2.3 billion during the three months ended June 30, 2022, which was included in goodwill and IPR&D impairment expense in the consolidated statements of operations. The goodwill was fully impaired as of June 30, 2022.

We also identified indicators of impairment related to the IPR&D intangible asset initially recognized as part of the acquisition of Singular Bio that it was more likely than not that the asset is impaired. The Company identified conditions during the period ended June 30, 2022 such as alternative technologies and uncertainties around the desired outcome of our in-development asset and other economic factors that raised issues with the realizability of our asset. As a result of our evaluation, we recognized a non-cash, pre-tax impairment charge of \$30.0 million during the three months ended June 30, 2022 related to the IPR&D intangible asset. The impairment charges are recorded in

Goodwill and IPR&D impairment expense in the consolidated statements of operations. The indefinite-lived intangible asset was fully impaired as of June 30, 2022. Additionally, we recognized a loss on disposal of property and equipment of \$4.8 million during the three months ended June 30, 2022 related to specific equipment that is no longer being utilized on this project and has no alternative future use. The loss on disposal is recorded in restructuring and other costs in the consolidated statements of operations.

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount.

A recoverability test was performed for the long-lived assets, including definite-lived intangibles, using the undiscounted cash flows approach, which included significant unobservable inputs including management's forecasts of projected revenue associated with future cash flows, and residual value. The cash flow estimates reflected the Company's assumptions about its use of the long-lived assets and eventual disposition of the asset group. We determined that our long-lived assets held and used, including intangible assets that are subject to amortization, did not have identifiable cash flows that are largely independent of the cash flows of other assets and liabilities and of other asset groups, because the assets are highly interrelated and interdependent. Therefore, the Company evaluated its long-lived assets for impairment on an entity-wide level. As a result of a recoverability test, we concluded that the carrying value of long-lived assets was recoverable at June 30, 2022. No impairment was recorded except for operating lease impairments, which are discussed under the heading "Leases" within Note 8, "Commitments and contingencies." We also recorded losses on disposal of assets pursuant to the strategic realignment, which are discussed in Note 11, "Restructuring and other costs."

6. Balance sheet components

Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	\$ 29,992	\$ 27,178
Work in progress	382	5,342
Finished goods	12	996
Total inventory	<u>\$ 30,386</u>	<u>\$ 33,516</u>

As part of the Company's strategic realignment, management decided to exit certain product offerings. During the year ended December 31, 2022, the Company wrote-off the remaining inventory related to these product offerings of \$14.3 million, which is included in cost of revenue in the consolidated statements of operations.

Property and equipment, net

Property and equipment consisted of the following (in thousands):

	December 31,	
	2022	2021
Leasehold improvements	\$ 74,108	\$ 31,159
Laboratory equipment	63,562	61,317
Computer equipment	13,712	15,452
Furniture and fixtures	1,428	2,130
Construction-in-progress	23,490	52,039
Other	2,996	925
Total property and equipment, gross	<u>179,296</u>	<u>163,022</u>
Accumulated depreciation and amortization	<u>(70,573)</u>	<u>(48,308)</u>
Total property and equipment, net	<u>\$ 108,723</u>	<u>\$ 114,714</u>

Depreciation expense was \$28.8 million, \$18.1 million and \$10.5 million for the years ended December 31, 2022, 2021 and 2020, respectively. Depreciation expense for the year ended December 31, 2022 includes accelerated depreciation of \$6.1 million from a change in the estimated useful lives of property and equipment related to the exit of certain product offerings.

As part of our strategic realignment, the Company decided to exit certain business lines, consolidate lab and office space, and reduce our international footprint. During the year ended December 31, 2022, we recognized losses on disposal of property and equipment of \$19.1 million, which is included in restructuring and other costs in our consolidated statement of operations. See Note 11, "Restructuring and other costs" for additional information.

See Note 5, "Goodwill and intangible assets" for additional information on the impairment assessment including long-lived assets and the related loss on disposal recognized during the three months ended June 30, 2022.

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued compensation and related expenses	\$ 25,315	\$ 35,877
Accrued expenses	23,628	32,136
Compensation and other liabilities associated with business combinations	5,335	11,622
Deferred revenue	4,814	9,431
Accrued interest	6,646	6,646
Accrued royalties	3,177	3,669
Other accrued liabilities	5,473	7,072
Total accrued liabilities	<u>\$ 74,388</u>	<u>\$ 106,453</u>

Other long-term liabilities

Other long-term liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Compensation and other liabilities associated with business combinations, non-current	\$ 769	\$ 27,919
Deferred revenue, non-current	50	663
Other	3,956	9,215
Total other long-term liabilities	<u>\$ 4,775</u>	<u>\$ 37,797</u>

7. Fair value measurements

Financial assets and liabilities are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The authoritative guidance establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques is summarized as follows:

Level 1—Observable inputs such as quoted prices (unadjusted) for identical instruments in active markets.

Level 2—Observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-derived valuations whose significant inputs are observable.

Level 3—Unobservable inputs that reflect the reporting entity's own assumptions.

The following tables set forth the fair value of our financial instruments that were measured at fair value on a recurring basis (in thousands):

December 31, 2022						
Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:						
Money market funds	\$ 158,931	\$ —	\$ 158,931	\$ 158,931	\$ —	\$ —
U.S. Treasury notes	193,685	1	193,563	193,563	—	—
U.S. government agency securities	96,006	55	96,048	—	96,048	—
Total financial assets	\$ 448,622	\$ 56	\$ 448,542	\$ 352,494	\$ 96,048	\$ —
Financial liabilities:						
Stock payable liability			\$ 744	\$ —	\$ —	\$ 744
Contingent consideration			25	—	—	25
Total financial liabilities			\$ 769	\$ —	\$ —	\$ 769

		December 31, 2022	
Reported as:			
Cash equivalents		\$	148,901
Restricted cash			10,030
Marketable securities			289,611
Total cash equivalents, restricted cash, and marketable securities		\$	448,542
Other long-term liabilities		\$	769

December 31, 2021						
Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:						
Money market funds	\$ 913,990	\$ —	\$ 913,990	\$ 913,990	\$ —	\$ —
U.S. Treasury notes	111,187	—	111,181	111,181	—	—
U.S. government agency securities	10,941	—	10,940	—	10,940	—
Total financial assets	\$ 1,036,118	\$ —	\$ 1,036,111	\$ 1,025,171	\$ 10,940	\$ —
Financial liabilities:						
Stock payable liability			\$ 20,925	\$ —	\$ —	\$ 20,925
Contingent consideration			1,875	—	—	1,875
Total financial liabilities			\$ 22,800	\$ —	\$ —	\$ 22,800

		December 31, 2021	
Reported as:			
Cash equivalents		\$	903,901
Restricted cash			10,030
Marketable securities			122,611
Total cash equivalents, restricted cash, and marketable securities		\$	1,036,542
Other long-term liabilities		\$	22,800

The following tables include a rollforward of the stock payable liability and contingent consideration classified within Level 3 of the fair value hierarchy (in thousands):

	<u>Stock Payable Liability</u>	<u>Contingent Consideration</u>
Fair value at December 31, 2021	\$ 20,925	\$ 1,875
Change in fair value	(15,906)	(1,850)
Settlements	(4,275)	—
Fair value at December 31, 2022	<u>\$ 744</u>	<u>\$ 25</u>

	<u>Stock Payable Liability</u>	<u>Contingent Consideration</u>
Fair value at December 31, 2020	\$ 39,237	\$ 796,639
Additions	31,522	—
Change in fair value	(25,196)	(386,646)
Settlements	(24,638)	(408,118)
Fair value at December 31, 2021	<u>\$ 20,925</u>	<u>\$ 1,875</u>

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. Our debt securities of U.S. government agencies are classified as Level 2 as they are valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to benchmark yields, interest rate curves, reported trades, broker/dealer quotes and reference data. At December 31, 2022, the remaining contractual maturities of available-for-sale securities ranged from one to five months. Interest income generated from our investments was \$6.8 million, \$6.9 million and \$4.0 million during the years ended December 31, 2022, 2021 and 2020, respectively.

The total fair value of investments with unrealized losses at December 31, 2022 was \$200.3 million. None of the available-for-sale securities held as of December 31, 2022 have been in an unrealized loss position for more than one year. The Company evaluates investments that are in an unrealized loss position for impairment as a result of credit loss. It was determined that no credit losses exist as of December 31, 2022, because the change in market value of those securities has resulted from fluctuations in market interest rates since the time of purchase, rather than a deterioration of the credit worthiness of the issuers. For marketable securities in an unrealized loss position, we assess our intent to sell, or whether it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. We intend to hold our marketable securities to maturity and it is unlikely that they would be sold before their cost bases are recovered. The cost of securities sold is based on the specific identification method.

Stock payable liabilities relate to certain indemnification hold-backs resulting from business combinations that are settled in shares of our common stock. We elected to account for these liabilities using the fair value option due to the inherent nature of the liabilities and the changes in value of the underlying shares that will ultimately be issued to settle the liabilities. The estimated fair value of these liabilities is classified as Level 3 and determined based upon the number of shares that are issuable to the sellers and the quoted closing price of our common stock as of the reporting date. The number of shares that will ultimately be issued is subject to adjustment for indemnified claims that existed as of the closing date for each acquisition. Changes in the number of shares issued and share price can significantly affect the estimated fair value of the liabilities. During the years ended December 31, 2022, 2021 and 2020, the change in fair value related to stock payable liabilities recorded to other income (expense), net was income of \$15.9 million and \$25.2 million and expense of \$37.5 million, respectively.

8. Commitments and contingencies

Leases

The Company has entered into various non-cancellable operating lease agreements for office and laboratory space domestically and internationally. The Company's current leases have remaining terms ranging from approximately 1 to 12 years, some of which include options to extend the leases. The renewal options were not included in the calculation of the operating lease assets and the operating lease liabilities as they are not reasonably

certain of being exercised. The security deposits for our operating leases are included in restricted cash in our consolidated balance sheets.

In 2015, we entered into a non-cancelable operating lease agreement for our headquarters and main production facility in San Francisco, California, which commenced in 2016 with an initial lease term extending through 2026. In 2020, we entered into a non-cancelable operating lease agreement for additional office and laboratory space in San Francisco, California, which commenced in 2021 and has an initial lease term extending through 2031. In 2021, we entered into a non-cancelable operating lease agreement for a new laboratory and production facility in Morrisville, North Carolina, which commenced in the same year with an initial lease term extending through 2035.

We have entered into various finance lease agreements to obtain laboratory equipment. The terms of our finance leases are generally three years and are typically secured by the underlying equipment. The portion of the future payments designated as principal repayment and related interest was classified as a finance lease obligation in our consolidated balance sheets. Finance lease assets are recorded within other assets in our consolidated balance sheets.

As part of the strategic realignment, we began cost reduction initiatives including lab and office space consolidation and a reduction in our international footprint. Under this plan, we decided to cease use of certain leased premises and actively began looking to sublease certain facilities, including the related leasehold improvements. We determined that the changes in the intended use of these locations represented an indicator of impairment and performed a test of recoverability on September 30, 2022. For operating leases where the carrying values of right-of-use assets were lower than the undiscounted cash flows expected through sublease, we impaired the right-of-use assets to their fair value. The fair value was determined by utilizing the discounted cash flow method under the income approach. The key inputs to this valuation were expected sublease rental income ranging from \$0.1 million to \$2.8 million and discount rates ranging from 5.00% to 8.50%. This fair value measurement is based on significant inputs not observable in the market and, therefore, represents a Level 3 measurement. During the three months ended September 30, 2022, we recognized an impairment charge of \$4.4 million related to the right-of-use assets and \$2.3 million for the related leasehold improvements, which are included in restructuring and other costs in our consolidated statements of operations.

In connection with the disposition of the RUO kit assets in December 2022, we entered into an agreement to sublease a portion of our offices in Boulder, Colorado. The sublease term is concurrent with the term of the master lease extending through January 31, 2025, unless earlier terminated and with no option to extend the sublease. Per the sublease agreement, the amount of sublease payments to us will equal the amount of the master lease payments resulting in no adjustments to the right-of-use asset and related lease liability. Sublease income for the year ended December 31, 2022 was immaterial. There was no sublease income for the years ended December 31, 2021 and 2020, respectively. See Note 4, "Business combinations and dispositions" for additional information regarding the disposition of the RUO kit assets.

Supplemental information regarding our operating and finance leases were as follows:

	Year Ended December 31,	
	2022	2021
Weighted-average remaining lease term:		
Operating leases	8.9 years	9.0 years
Finance leases	1.8 years	2.4 years
Weighted-average discount rate:		
Operating leases	6.7 %	7.0 %
Finance leases	7.3 %	7.2 %
Cash payments included in the measurement of lease liabilities (in millions):		
Operating leases	\$ 22.4	\$ 18.3
Finance leases	\$ 6.2	\$ 2.9

The components of lease costs, which were included in cost of revenue, research and development, and general and administrative expenses in our consolidated statements of operations, were as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Operating lease costs	\$ 24,671	\$ 21,151	\$ 11,329
Finance lease costs:			
Amortization of right-of-use assets	4,778	3,488	2,084
Interest on lease liabilities	840	496	—
Total lease costs	\$ 30,289	\$ 25,135	\$ 13,413

Future payments under operating and finance leases as of December 31, 2022 are as follows (in thousands):

	<u>Operating leases</u>	<u>Finance leases</u>
2023	\$ 23,691	\$ 5,595
2024	28,308	3,344
2025	17,465	495
2026	23,989	—
2027	15,863	—
Thereafter	91,177	—
Future non-cancelable minimum lease payments	<u>200,493</u>	<u>9,434</u>
Less: interest	(51,507)	(533)
Total lease liabilities	<u>148,986</u>	<u>8,901</u>
Less: current portion	(14,600)	(5,121)
Lease obligations, net of current portion	<u>\$ 134,386</u>	<u>\$ 3,780</u>

Operating lease maturity amounts included in the table above do not include sublease income expected to be received under our sublease. Under the sublease agreement, we expect to receive sublease income for fiscal years ending December 31, 2023, 2024 and 2025 of \$0.9 million, \$0.9 million and \$0.1 million, respectively.

Debt financing

In October 2020, we entered into a credit agreement with a financial institution under which we borrowed \$135.0 million (the "2020 Term Loan") concurrent with the closing of the ArcherDX acquisition. The 2020 Term Loan is secured by a first priority lien on all of our and our subsidiaries' assets, and is guaranteed by us and our subsidiaries. The 2020 Term Loan bears interest at an annual rate equal to three-month LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75%. If three-month LIBOR can no longer be determined or if the applicable governmental authority ceases to supervise or sanction such rates, then we will endeavor to agree with the administrative agent, an alternate rate of interest that gives due consideration to the then prevailing market convention for determining interest for comparable loans in the United States, provided that until such alternative rate of interest is agreed, the 2020 Term Loan shall bear interest at the *Wall Street Journal* Prime Rate. The three-month LIBOR is expected to be available and representative through June 30, 2023. The 2020 Term Loan will mature on (i) June 1, 2024, if at such time our 2024 Notes (defined below) are outstanding and are due to mature on September 1, 2024 (provided that if, prior to such date, the maturity date of at least 80% of the 2024 Notes is extended to a date that is prior to September 1, 2025, the maturity date for the 2020 Term Loan will be automatically extended to a date that is 90 days prior to such 2024 Notes maturity date as extended), or (ii) otherwise, on June 1, 2025. The full amount of the 2020 Term Loan is due upon maturity. If the 2020 Term Loan is prepaid (whether such prepayment is optional or mandatory), we must pay a prepayment fee of 6% if the prepayment occurs prior to the third anniversary of the closing date or 4% if the prepayment occurs after the third anniversary of the closing date and we must also pay a make-whole fee if the prepayment occurs prior to the second anniversary of the closing date. In connection with the 2020 Term Loan, we issued warrants to purchase 1.0 million shares of our common stock with an exercise price of \$16.85 per share, exercisable through October 2027. The warrants, which were classified as equity, were recorded at an amount based on the allocated proceeds and do not require subsequent remeasurement. In October 2020, these warrants were exercised in full through net settlement resulting in the issuance of 0.7 million shares.

The credit agreement contains customary events of default and covenants, including among others, covenants limiting our ability to incur debt, incur liens, undergo a change in control, merge with or acquire other entities, make investments, pay dividends or other distributions to holders of our equity securities, repurchase stock, and dispose of assets, in each case subject to certain customary exceptions. In addition, the credit agreement contains financial covenants that require us to maintain a minimum cash balance and minimum quarterly revenue levels.

As of December 31, 2022, the fair value of the 2020 Term Loan was \$130.0 million. The estimated fair value of the 2020 Term Loan, which use Level 2 fair value inputs, was determined based on a discounted cash flow approach using the contractual term of the loan, market-based parameters such as the three-month LIBOR forward rate, and an estimate for our standalone credit risk. Debt discounts, including debt issuance costs, related to the 2020 Term Loan of \$32.8 million were recorded as a direct deduction from the debt liability and are being amortized to interest expense over the term of the 2020 Term Loan. Interest expense related to our debt financings, excluding the impact of our convertible senior notes (defined below), was \$24.3 million, \$23.7 million and \$7.4 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Convertible senior notes

Convertible senior notes due 2024

In September 2019, we issued, at par value, \$350.0 million aggregate principal amount of 2.00% convertible senior notes due 2024 (the "2024 Notes") in a private offering. The 2024 Notes are senior unsecured obligations and will mature on September 1, 2024, unless earlier converted, redeemed or repurchased. The 2024 Notes bear cash interest at a rate of 2.0% per year, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on March 1, 2020.

Upon conversion, the 2024 Notes will be convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate for the 2024 Notes is 33.6293 shares of our common stock per \$1,000 principal amount of the 2024 Notes (equivalent to an initial conversion price of approximately \$29.74 per share of common stock).

If we undergo a fundamental change (as defined in the indenture governing the 2024 Notes), the holders of the 2024 Notes may require us to repurchase all or any portion of their 2024 Notes for cash at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased plus accrued and unpaid interest to, but excluding, the redemption date.

The 2024 Notes will be convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding March 1, 2024, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on December 31, 2019 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2024 Notes on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per \$1,000 principal amount of 2024 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (3) if we call any or all of the 2024 Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or (4) upon the occurrence of specified corporate events. On or after March 1, 2024 until the close of business on the business day immediately preceding the maturity date, holders may convert their 2024 Notes at any time, regardless of the foregoing circumstances. Since issuance, these notes were convertible at the option of the holders beginning on January 1, 2021 and April 1, 2021 due to the sale price of our common stock during the quarters ended December 31, 2020 and March 31, 2021, respectively. The notes were not convertible during the year ended December 31, 2022 and there have been no significant conversions in the periods in which they were convertible.

We may redeem for cash all or any portion of the 2024 Notes, at our option, on or after September 6, 2022 and on or before the 30th scheduled trading day immediately before the maturity date if the last reported sale price of the common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

Convertible senior notes due 2028

In April 2021, we issued, at 99% of par value, \$1,150.0 million aggregate principal amount of 1.5% convertible senior notes due 2028 (the "2028 Notes") in a private offering. The 2028 Notes are senior unsecured obligations and will mature on April 1, 2028, unless earlier converted, redeemed or repurchased. The 2028 Notes bear cash interest at a rate of 1.5% per year, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on October 1, 2021. Upon conversion, the 2028 Notes will be convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

The 2028 Notes will be convertible at the option of the holder at any time until the second scheduled trading day prior to the maturity date, including in connection with a redemption by us. The 2028 Notes will be convertible into shares of our common stock based on an initial conversion rate of 23.1589 shares of common stock per \$1,000 principal amount of the 2028 Notes (which is equal to an initial conversion price of \$43.18 per share), in each case subject to customary anti-dilution and other adjustments as a result of certain extraordinary transactions. None of the 2028 Notes have been converted to date.

We may not redeem the 2028 Notes prior to April 6, 2025. On or after April 6, 2025, the 2028 Notes will be redeemable by us in the event that the closing sale price of our common stock has been at least 150% of the

conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide the redemption notice at a redemption price of 100% of the principal amount of such 2028 Notes, plus accrued and unpaid interest to, but excluding, the redemption date.

With certain exceptions, upon a change of control of the Company or the failure of our common stock to be listed on certain stock exchanges, the holders of the 2028 Notes may require that we repurchase in cash all or part of the principal amount of the Notes at a repurchase price of 100% of the principal amount of the 2028 Notes to be repurchased, plus unpaid interest to, but excluding, the maturity date.

Summary of convertible senior notes

We adopted the provisions of ASU 2020-06 on January 1, 2021. See Note 2, "Summary of significant accounting policies" for additional information. Our 2024 Notes and 2028 Notes (collectively, our "Convertible Senior Notes") consisted of the following (in thousands):

	December 31,	
	2022	2021
Outstanding principal	\$ 1,499,996	\$ 1,499,996
Unamortized debt discount and issuance costs	(29,213)	(35,858)
Net carrying amount, liability component	<u>\$ 1,470,783</u>	<u>\$ 1,464,138</u>

As of December 31, 2022, the fair value of the 2024 Notes and 2028 Notes was \$261.6 million and \$576.7 million, respectively. The estimated fair value of the 2024 Notes and 2028 Notes, which use Level 2 fair value inputs, was determined based on the estimated or actual bid prices in an over-the-counter market and/or market conditions including the price and volatility of our common stock and comparable company information. We recognized \$30.8 million, \$24.9 million and \$22.0 million of interest expense related to our Convertible Senior Notes during the years ended December 31, 2022, 2021 and 2020, respectively. Of the interest expense recognized during the years ended December 31, 2022, 2021 and 2020, \$6.7 million, \$5.3 million and \$1.9 million, respectively, was related to amortization of issuance costs and the remainder was related to contractual interest incurred.

Other commitments

In the normal course of business, we enter into various purchase commitments primarily related to service agreements and laboratory supplies. At December 31, 2022, our total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were as follows (in thousands):

2023	19,756
2024	11,065
2025	1,844
2026	500
2027	250
Total	<u>\$ 33,415</u>

Guarantees and indemnification

As permitted under Delaware law and in accordance with our bylaws, we indemnify our directors and officers for certain events or occurrences while the officer or director is or was serving in such capacity. The maximum amount of potential future indemnification is unlimited; however, we maintain director and officer liability insurance. This insurance allows the transfer of the risk associated with our exposure and may enable us to recover a portion of any future amounts paid. We believe the fair value of these indemnification agreements is minimal. Accordingly, we did not record any liabilities associated with these indemnification agreements at December 31, 2022 or 2021.

Contingencies

We are and may from time to time be involved in various legal proceedings and claims arising in the ordinary course of business. Legal proceedings, including litigation, government investigations and enforcement actions could result in material costs, occupy significant management resources and entail civil and criminal penalties, even if we ultimately prevail. If an investigation results in a proceeding against us, an adverse outcome could include us being required to pay treble damages, and incur attorneys' fees, civil or criminal penalties and other adverse actions that could materially and adversely affect our business, financial condition and results of operations. While we believe any

such claims are unsubstantiated, and we believe we are in compliance with applicable laws and regulations applicable to our business, the resolution of any such claims could be material.

We were not a party to any material legal proceedings at December 31, 2022, or at the date of this report except for matters listed below. We cannot currently predict the outcome of these actions.

Natera, Inc.

On January 27, 2020, Natera filed a lawsuit against ArcherDX (a subsidiary of Invitae effective October 2, 2020) in the United States District Court for the District of Delaware, alleging that ArcherDX's products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814. On March 25, 2020, ArcherDX filed an answer denying Natera's allegations and asserting certain affirmative defenses and counterclaims, including that U.S. Patent No. 10,538,814 is invalid and not infringed. On April 15, 2020, Natera filed an answer denying ArcherDX's counterclaims and filed an amended complaint alleging that ArcherDX's products using AMP chemistry, including STRATAFIDE, PCM, LiquidPlex, ArcherMET, FusionPlex, and VariantPlex, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, U.S. Patent No. 10,590,482, and U.S. Patent No. 10,597,708, each of which are held by Natera. Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of such patents. On May 13, 2020, ArcherDX filed an answer to Natera's amended complaint denying Natera's allegations and asserting certain affirmative defenses and counterclaims, including that the asserted patents are invalid and not infringed. On June 3, 2020, Natera filed an answer denying ArcherDX's counterclaims. On June 4, 2020, ArcherDX filed a motion seeking dismissal of Natera's infringement claims against STRATAFIDE, PCM, and ArcherMET, and for a judgment that U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On August 6, 2020, Natera filed another complaint against ArcherDX in the United States District Court for the District of Delaware alleging that ArcherDX's products using AMP chemistry, including STRATAFIDE, PCM, LiquidPlex, ArcherMET, and VariantPlex, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,731,220. Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of the patent. On October 13, 2020, the court issued an order denying ArcherDX's motion for dismissal of Natera's infringement claims against STRATAFIDE, PCM, and ArcherMET, and declined to enter judgment that U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On January 12, 2021, the court issued an order granting Natera leave to amend its complaint to add Invitae as a co-defendant and plead allegations that ArcherDX and Invitae induce end-users to infringe the patents-in-suit. Natera filed its second amended complaint ("Second Amended Complaint") on the same day, with service completed on January 15, 2021. ArcherDX and Invitae filed answers to the Second Amended Complaint on January 26, 2021 and February 5, 2021, respectively, denying Natera's allegations and restating certain affirmative defenses and counterclaims of non-infringement and invalidity. The litigations have now been consolidated for all purposes. A claim construction order was issued on June 28, 2021. On October 27, 2021, Natera filed its third amended complaint ("Third Amended Complaint") to add a Certificate of Correction to U.S. Patent No. 10,590,482. On November 3, 2021, ArcherDX filed its answer and counterclaims to Natera's Third Amended Complaint, adding an inequitable conduct defense and declaratory judgment counterclaims. Discovery concluded in December 2021. On January 21, 2022, Natera, ArcherDX and Invitae moved for summary judgment, wherein Natera seeks a determination on certain legal and equitable defenses and ArcherDX and Invitae seek a determination of non-infringement and invalidity of the asserted patents. The court denied the parties' respective summary judgment motions by order dated February 6, 2023. Trial is set for May 8, 2023.

In addition, on October 6, 2020, Natera filed a complaint against Genosity in the United States District Court for the District of Delaware, alleging that Genosity's use of its AsTra products, and the manufacture, use, sale, and offer for sale of such products, infringes U.S. Patent No. 10,731,220. Natera's complaint further alleges that Genosity's accused products use ArcherDX's ctDNA and region-specific primers. Genosity filed an answer to the complaint on February 15, 2021, denying Natera's allegations and setting forth affirmative defenses and counterclaims of non-infringement, invalidity and unenforceability due to inequitable conduct. On March 8, 2021, Natera filed a motion to dismiss and strike certain affirmative defenses and counterclaims brought by Genosity relating to inequitable conduct. The court denied that motion on March 14, 2022. The court granted an order granting the parties' stipulated request to stay the case on April 1, 2022.

QIAGEN Sciences

On July 10, 2018, ArcherDX and the General Hospital Corporation d/b/a Massachusetts General Hospital, which we refer to as MGH, filed a lawsuit in the United States District Court for the District of Delaware against QIAGEN Sciences, LLC, QIAGEN LLC, QIAGEN Beverly, Inc., QIAGEN Gaithersburg, Inc., QIAGEN GmbH and QIAGEN N.V., which is collectively referred to herein as QIAGEN, and a named QIAGEN executive who was a former

member of ArcherDX's board of directors, alleging several causes of action, including infringement of the '810 Patent, trade secret misappropriation, breach of fiduciary duty, false advertising, tortious interference and deceptive trade practices. The '810 Patent relates to methods for preparing a nucleic acid for sequencing and aspects of ArcherDX's AMP technology. On October 30, 2019, with the permission of the Court, ArcherDX amended ArcherDX's complaint to add a claim for infringement of the '597 Patent. The '597 Patent relates to methods of preparing and analyzing nucleic acids, such as by enriching target sequences prior to sequencing, and aspects of ArcherDX's AMP technology. The QIAGEN products that ArcherDX alleges infringe the '810 Patent and the '597 Patent include, but are not limited to, QIAseq Targeted DNA Panels, QIAseq Targeted RNAscan Panels, QIAseq Index Kits and QIAseq Immune Repertoire RNA Library Kits. ArcherDX is seeking, among other things, damages for ArcherDX's lost profits due to QIAGEN's infringement and a permanent injunction enjoining QIAGEN from marketing and selling the infringing products and from using ArcherDX's trade secrets. On December 5, 2019, QIAGEN and the named QIAGEN executive submitted their answer denying the allegations in ArcherDX's complaint and asserting affirmative defenses that, among other things, the '810 Patent and '597 Patent are not infringed by QIAGEN's products, that both patents are invalid, and that the complaint fails to state any claim for which relief may be granted. On March 1, 2021, each of ArcherDX and QIAGEN moved for summary judgment on issues relating to infringement and validity of ArcherDX's patents, breach of fiduciary duty and trade secret misappropriation. On June 18, 2021, ArcherDX informed the court that it would not assert the following claims to streamline the issues for trial: trade secret misappropriation, false advertising, deceptive trade practices, and tortious interference. The court denied QIAGEN's motion for summary judgment on trade secret misappropriation as moot on June 21, 2021, denied QIAGEN's motion for summary judgment on breach of fiduciary duty on July 26, 2021, and granted QIAGEN's motion for summary judgment of no literal infringement of the '810 Patent on August 21, 2021. Trial proceeded on August 23 through August 27, 2021, resulting in a unanimous jury verdict, which found that: (i) all asserted claims of the '810 and '597 Patents are valid, (ii) QIAGEN willfully infringed the asserted claims of the '810 patent (under the doctrine of equivalents) and the '597 patent (literal infringement), and (iii) ArcherDX and MGH are entitled to recover approximately \$4.7 million in damages. On September 30, 2022, the court issued an order denying QIAGEN's post-trial motion for a new trial or altered verdict, granting QIAGEN's post-trial motion to reduce damages to approximately \$4.0 million, granting ArcherDX's post-trial motion for ongoing royalty at a rate of 7% along with supplemental damages and interest, and denying ArcherDX's motion for an injunction with leave to renew after an evidentiary hearing. No date has been set for the hearing on ArcherDX's request for an injunction.

9. Stockholders' equity

Shares outstanding

Shares of convertible preferred and common stock were as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Convertible preferred stock:			
Shares outstanding, beginning of period	—	125	125
Conversion into common stock	—	(125)	—
Shares outstanding, end of period	—	—	125
Common stock:			
Shares outstanding, beginning of period	228,116	185,886	98,796
Common stock issued in private placement	—	—	16,320
Common stock issued in connection with public offering	2,429	8,932	24,005
Common stock issued on exercise of stock options, net	159	2,068	2,659
Common stock issued pursuant to vesting of RSUs	10,486	4,325	5,304
Common stock issued pursuant to exercises of warrants	—	208	968
Common stock issued pursuant to employee stock purchase plan	2,231	654	671
Common stock issued pursuant to acquisitions	2,141	25,918	37,163
Common stock issued upon conversion of preferred stock	—	125	—
Shares outstanding, end of period	245,562	228,116	185,886

Common Stock

As of December 31, 2022, we had 600 million shares of common stock authorized with a par value of \$0.0001. The number of authorized shares increased from 400 million to 600 million during the year ended December 31, 2022.

Convertible preferred stock

In August 2017, in a private placement to certain accredited investors, we issued shares of our Series A convertible preferred stock which are convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like. The Series A convertible preferred stock is a non-voting common stock equivalent with a par value of \$0.0001 and has the right to receive dividends first or simultaneously with payment of dividends on common stock. In the event of any liquidation or dissolution of the Company, the Series A preferred stock is entitled to receive \$0.001 per share prior to the payment of any amount to any holders of capital stock ranking junior to the Series A preferred stock and thereafter shall participate pari passu with the holders of our common stock (on an as-if-converted-to-common-stock basis). During the year ended December 31, 2021, 124,913 shares of Series A convertible preferred stock were converted into 124,913 shares of common stock. As of December 31, 2022 and 2021, we had 20 million shares of preferred stock authorized, of which 3,458,823 shares were designated as Series A convertible preferred stock. As of December 31, 2022 and 2021, there were no shares of preferred stock or Series A convertible preferred stock outstanding.

Sales Agreements

In May 2021, we entered into a sales agreement (the "2021 Sales Agreement") with Cowen and Company, LLC ("Cowen") under which we may offer and sell from time to time at our sole discretion shares of our common stock through Cowen as our sales agent, in an aggregate amount not to exceed \$400.0 million. Per the terms of the agreement, Cowen will receive a commission of up to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2021 Sales Agreement.

During the year ended December 31, 2022, we sold a total of 2.4 million shares of common stock under the 2021 Sales Agreement at an average price of \$3.99 per share, for gross proceeds of \$10.0 million and net proceeds of \$9.7 million. During the year ended December 31, 2020, we sold a total of 3.6 million shares of common stock under the common stock sales agreement entered into with Cowen in August 2018 at an average price of \$26.33 per share, for gross proceeds of \$93.7 million and net proceeds of \$90.7 million.

Public offerings

In January 2021, we sold, in an underwritten public offering, an aggregate of 8.9 million shares of our common stock at a price of \$51.50 per share, for gross proceeds of \$460.0 million and net proceeds of approximately \$434.3 million after deducting underwriting discounts and commissions and offering expenses.

In April 2020, we sold, in an underwritten public offering, an aggregate of 20.4 million shares of our common stock at a price of \$9.00 per share, for gross proceeds of \$184.0 million and net proceeds of \$173.0 million after deducting underwriting discounts and commissions and offering expenses.

Private placement

In connection with our acquisition of ArcherDX, in June 2020 we entered into a definitive agreement to sell \$275.0 million in common stock in a private placement at a price of \$16.85 per share. We received net proceeds of \$263.7 million after deducting placement fees and offering expenses upon the closing of the private placement in October 2020, concurrently with our acquisition of ArcherDX.

10. Stock incentive plans

Stock incentive plans

In 2010, we adopted the 2010 Incentive Plan (the "2010 Plan"). The 2010 Plan provides for the granting of stock-based awards to employees, directors and consultants under terms and provisions established by our board of directors. Under the terms of the 2010 Plan, options may be granted at an exercise price not less than the fair market value of our common stock. For employees holding more than 10% of the voting rights of all classes of stock, the exercise prices for incentive and nonstatutory stock options must be at least 110% of fair market value of our common stock on the grant date, as determined by our board of directors. The terms of options granted under the 2010 Plan may not exceed ten years.

In January 2015, we adopted the 2015 Stock Incentive Plan (the “2015 Plan”), which became effective upon the closing of our initial public offering. Shares outstanding under the 2010 Plan were transferred to the 2015 Plan upon effectiveness of the 2015 Plan. The 2015 Plan provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 through January 1, 2025. In addition, shares subject to awards under the 2010 Plan that are forfeited or terminated will be added to the 2015 Plan. The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock units, stock appreciation rights and other forms of equity compensation, all of which may be granted to employees, including officers, non-employee directors and consultants. Additionally, the 2015 Plan provides for the grant of cash-based awards.

Options granted generally vest over a period of four years. Typically, the vesting schedule for options granted to newly hired employees provides that 1/4 of the award vests upon the first anniversary of the employee’s date of hire, with the remainder of the award vesting monthly thereafter at a rate of 1/48 of the total shares subject to the option. All other options typically vest in equal monthly installments over the four-year vesting schedule. Upon the acquisition of ArcherDX in October 2020, any option that was outstanding was converted into a fully vested option to purchase a share of our common stock, which resulted in the issuance of options to purchase 3.7 million shares of our common stock.

RSUs generally vest ratably in annual installments over a period of three years, commencing on the first anniversary of the grant date, with certain awards that include a portion that vests immediately upon grant. The vesting schedule for the 2022 grants approved in April 2022 provides that the awards vest ratably in quarterly installments over a period of two years, with certain awards that include a portion that vests immediately upon grant. Grants to the executive team in 2022 vest ratably in annual installments over a period of three years. We have also granted certain awards in connection with our management incentive plan that vest over a period of two years. In June 2019, we granted time-based RSUs in connection with an acquisition and PRSUs that vested based on the achievement of performance conditions, both of which were fully vested as of December 31, 2022. In December 2020, we granted RSUs in connection with an asset acquisition which were fully vested as of December 31, 2022.

Under our management incentive compensation plan, in July 2019 we granted PRSUs to our executive officers as well as other specified senior level employees based on the level of achievement of a specified 2019 revenue goal. One-third of the 0.8 million shares that were ultimately awarded under this plan vested during the year ended December 31, 2020 and the remaining shares vested through March 2022. In June 2020, we granted 0.3 million PRSUs under this plan which are based on the level of achievement of a specified 2020 cash burn goal. Upon achievement of the specified 2020 cash burn goal, 0.3 million shares were ultimately awarded and vested in 2021 over a one-year period. These PRSUs had a grant date fair value of \$4.2 million based on an estimated issuance of 0.3 million shares and expectation of the performance conditions. During the years ended December 31, 2022, 2021 and 2020, \$2.7 million, \$2.7 million and \$0.7 million were recorded as stock-based compensation expense related to the awards, respectively.

Activity under the 2010 Plan and the 2015 Plan is set forth below (in thousands, except per share data and years):

	Shares Available For Grant	Stock Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Balances at December 31, 2021	10,242	3,034	\$ 11.98	5.5	\$ 16,431
Additional shares reserved	9,125	—			
Options granted	(1,121)	1,121	\$ 3.03		
Options cancelled	1,455	(1,455)	\$ 12.04		
Options exercised	—	(159)	\$ 4.06		
RSUs and PRSUs granted	(12,508)	—			
RSUs and PRSUs cancelled	5,432	—			
Balances at December 31, 2022	<u>12,625</u>	<u>2,541</u>	\$ 8.49	6.6	\$ 16
Options exercisable at December 31, 2022		<u>1,384</u>	\$ 11.21	4.1	\$ 16
Options vested and expected to vest at December 31, 2022		<u>2,383</u>	\$ 8.84	6.1	\$ 16

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of our common stock for stock options that were in-the-money.

The weighted-average fair value of options to purchase common stock granted was \$2.07, \$22.46 and \$10.10 in the years ended December 31, 2022, 2021 and 2020, respectively.

The total grant-date fair value of options to purchase common stock vested was \$1.8 million, \$2.4 million and \$2.8 million in the year ended December 31, 2022, 2021, and 2020, respectively.

The intrinsic value of options to purchase common stock exercised was \$0.7 million, \$55.0 million and \$104.4 million in the years ended December 31, 2022, 2021 and 2020, respectively.

The following table summarizes RSU, including PRSU, activity (in thousands, except per share data):

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance at December 31, 2021	16,247	\$ 26.21
RSUs granted	11,622	\$ 5.58
Time-based RSUs and PRSUs granted - variable	886	\$ 2.47
RSUs vested	(11,428)	\$ 23.03
RSUs cancelled	(5,432)	\$ 16.67
Balance at December 31, 2022	<u>11,895</u>	<u>\$ 11.70</u>

2015 ESPP

In January 2015, we adopted the 2015 ESPP, which became effective upon the closing of the IPO. Employees participating in the ESPP may purchase common stock at 85% of the lesser of the fair market value of common stock on the purchase date or last trading day preceding the offering date. At December 31, 2022, cash received from payroll deductions pursuant to the ESPP was \$1.3 million.

The ESPP provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 and continuing through January 1, 2025. At December 31, 2022, a total of 2.1 million shares of common stock are reserved for issuance under the ESPP.

Stock-based compensation

We use the grant date fair value of our common stock to value options when granted. In determining the fair value of stock options and ESPP purchases, we use the Black-Scholes option-pricing model and, for stock options, the assumptions discussed below. Each of these inputs is subjective and its determination generally requires significant judgment. The fair value of RSU and PRSU awards is based on the grant date share price. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and RSUs and on an accelerated basis for PRSUs.

Fair value of common stock—The fair value of each share of common stock is based on the closing price of our common stock on the date of grant as reported on the NYSE.

Expected term—The expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method (based on the midpoint between the vesting date and the end of the contractual term).

Expected volatility—We estimate expected volatility based on the historical volatility of our common stock over a period equal to the expected term of stock option grants and RSUs and over the expected six-month term ESPP purchase periods.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Dividend yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

The fair value of share-based payments for stock options granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model based on the following assumptions:

	Year Ended December 31,		
	2022	2021	2020
Fair value of common stock	\$2.85 - \$5.22	\$34.90	\$16.17 - \$16.55
Expected term (in years)	6.0	6.0	6.0
Expected volatility	77.6%	73.5%	71.0%
Risk-free interest rate	3.0%	1.1%	0.5%

The fair value of shares purchased pursuant to the ESPP is estimated using the Black-Scholes option pricing model. For the years ended December 31, 2022, 2021 and 2020, the weighted-average grant date fair value per share for the ESPP was \$2.34, \$8.10 and \$10.98, respectively.

The fair value of the shares purchased pursuant to the ESPP was estimated using the following assumptions:

	Year Ended December 31,		
	2022	2021	2020
Expected term (in years)	0.5	0.5	0.5
Expected volatility	200.6%	66.1%	105.7%
Risk-free interest rate	3.6%	0.0%	0.1%

The following table summarizes stock-based compensation expense for the years ended December 31, 2022, 2021 and 2020, included in the consolidated statements of operations (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Cost of revenue	\$ 6,868	\$ 12,033	\$ 8,713
Research and development	113,843	92,407	91,762
Selling and marketing	12,897	15,641	14,418
General and administrative	35,378	59,994	43,854
Restructuring and other costs	30,318	—	—
Total stock-based compensation expense	\$ 199,304	\$ 180,075	\$ 158,747

Stock-based compensation expense included in restructuring and other costs was related to the accelerated vesting of RSUs held by certain employees whose employment was terminated as part of the strategic realignment. Pursuant to the terms and conditions of the Ciitizen transaction, employees were deemed vested in any unvested RSUs at the time of their termination. See Note 11, "Restructuring and other costs" for additional information.

At December 31, 2022, unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was \$3.4 million, which we expect to recognize on a straight-line basis over a weighted-average period of 3.3 years. Unrecognized compensation expense related to RSUs, including PRSUs, and awards that are contingently issuable upon the completion of certain milestones related to our acquisitions of ArcherDX and IntelliGene Health Informatics, LLC at December 31, 2022, net of estimated forfeitures, was \$154.0 million, which we expect to recognize on a straight-line basis over a weighted-average period of 1.5 years.

11. Restructuring and other costs

On July 18, 2022, we initiated a strategic realignment of our operations to reduce operating costs and drive future growth aligned with our core genetic testing and data platform and patient network. The strategic realignment includes a reduction in workforce, lab and office space consolidation, portfolio optimization, decrease in other operating expenses, as well as a reduced international footprint. Under this strategic realignment, we reduced our workforce by approximately 1,000 employees with a majority of these employees separating from the Company by September 30, 2022 and the remaining affected employees transitioning over varying periods of time up to 12 months. Employees who were impacted by the restructuring were eligible to receive severance benefits contingent upon an impacted employee's execution (and non-revocation, where applicable) of a separation agreement, which included a general release of claims against us.

The following table summarizes the expenses related to our strategic realignment recognized in restructuring and other costs in our consolidated statement of operations (in thousands):

	Year Ended December 31,	
	2022	
Employee severance and benefits	\$	65,556
Impairments and losses on disposals of long-lived assets		60,507
Other restructuring costs		14,268
Total restructuring and other costs	\$	140,331

Employee severance and benefits are comprised of severance, other termination benefit costs, and stock-based compensation expense for the acceleration of RSUs related to workforce reductions. See Note 10, "Stock incentive plans" for additional information about the accelerated vesting of RSUs. Asset impairments and losses on asset disposals include operating lease impairments, losses on disposals of property and equipment and leasehold

improvements associated with exiting lines of business, consolidating lab and office space, and reducing our international footprint. See Note 8, "Commitments and contingencies" under the heading "Leases" for additional information about operating lease impairments. See Note 5, "Goodwill and intangible assets" for additional information about the loss on disposal of property and equipment related to the Singular Bio acquisition and Note 6, "Balance sheet components" for additional information about losses on disposal of property and equipment. Other restructuring costs include the write-off of prepaid assets related to the exit of certain product offerings, legal and professional fees, and contract exit costs.

We expect to incur additional employee severance and benefits expenses up to \$1.2 million, and additional other restructuring costs primarily related to third-party costs up to \$3.5 million. This reflects the best estimate of the Company, which may be revised in subsequent periods as the strategic realignment progresses.

The following table summarizes the changes in liabilities associated with our strategic realignment initiatives, including restructuring and other costs incurred and cash payments as of December 31, 2022 (in thousands):

	Employee severance and benefits	Other restructuring costs	Total
Beginning balance	\$ —	\$ —	\$ —
Accruals	35,237	7,405	42,642
Payments	(32,974)	(5,464)	(38,438)
Balance at December 31, 2022	<u>\$ 2,263</u>	<u>\$ 1,941</u>	<u>\$ 4,204</u>

The restructuring liabilities are included in accrued liabilities in the consolidated balance sheets. We expect that substantially all of the remaining accrued restructuring liabilities will be paid in cash over the next 12 months. The charges recognized in the roll forward of our accrued restructuring liabilities do not include items charged directly to expense for losses on asset disposals, accelerated vesting of RSUs, and other periodic exit costs, as those items are not reflected in our restructuring liabilities in our consolidated balance sheets.

12. Income taxes

We recorded a benefit for income taxes in the years ended December 31, 2022, 2021 and 2020. The components of net loss before taxes by U.S. and foreign jurisdictions are as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
United States	\$ 3,147,669	\$ 414,657	\$ 712,409
Foreign	3,528	1,206	1,861
Total	<u>\$ 3,151,197</u>	<u>\$ 415,863</u>	<u>\$ 714,270</u>

The components of the provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Current:			
Foreign	1,338	(2,069)	(171)
Total current benefit (expense) for income taxes	<u>1,338</u>	<u>(2,069)</u>	<u>(171)</u>
Deferred:			
Federal	22,368	28,348	94,279
State	19,512	8,809	17,730
Foreign	1,686	1,769	262
Total deferred benefit for income taxes	<u>43,566</u>	<u>38,926</u>	<u>112,271</u>
Total income tax benefit	<u>\$ 44,904</u>	<u>\$ 36,857</u>	<u>\$ 112,100</u>

The following table presents a reconciliation of the tax expense computed at the statutory federal rate and our tax expense for the periods presented:

	Year Ended December 31,		
	2022	2021	2020
U.S. federal taxes at statutory rate	21.0 %	21.0 %	21.0 %
State taxes (net of federal benefit)	0.9 %	7.3 %	3.4 %
Stock-based compensation	(1.2)%	(1.2)%	(1.6)%
Research and development credits	0.4 %	3.8 %	1.1 %
Non-deductible expenses	— %	(0.9)%	(0.7)%
Foreign tax differential	0.1 %	(0.1)%	— %
Acquisition contingent liabilities	0.1 %	18.5 %	(0.8)%
Non-deductible impairment expense	(14.9)%	— %	— %
Change in valuation allowance	(4.9)%	(39.5)%	(6.7)%
Total	1.5 %	8.9 %	15.7 %

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	As of December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 595,301	\$ 530,663
Tax credits	49,615	36,188
R&D capitalization and amortization	72,358	6,202
Revenue recognition differences	—	2,560
Leasing liabilities	36,986	34,403
Accruals and other	41,198	36,689
Gross deferred tax assets	795,458	646,705
Valuation allowance	(542,900)	(386,950)
Total deferred tax assets	252,558	259,755
Deferred tax liabilities:		
Amortization and depreciation	(216,899)	(277,719)
Revenue recognition differences	(14,180)	—
Leasing assets	(29,609)	(33,732)
Total deferred tax liabilities	(260,688)	(311,451)
Net deferred tax liabilities	\$ (8,130)	\$ (51,696)

The Company historically established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets. In 2022 the Company released approximately \$41.9 million of its valuation allowance, primarily due to the release of federal and state valuation allowances as a result of the reclassification of ArcherDX's IVD and PCM in-process research and development intangibles from indefinite-lived intangibles to developed technology, which enabled the associated deferred tax liability to serve as a source of income to existing finite-lived deferred tax assets for which a valuation allowance had previously been established.

Effective for tax years beginning on or after January 1, 2022, pursuant to the Tax Cuts and Jobs Act of 2017, companies are required to capitalize and amortize Internal Revenue Code Section 174 research and experimental expenses paid or incurred over five years for research and development performed in the United States and 15 years for research and development performed outside of the United States. As a result of the Internal Revenue Code Section 174 research and experimental expense capitalization, the Company recognized a deferred tax asset for the future tax benefit of the amortization deductions with offsetting increase in the valuation allowance on deferred tax assets.

Due to the overall increase of deferred tax assets, the Company's valuation allowance also increased from the prior year. The Company's valuation allowance increased by \$155.9 million, \$177.6 million, and \$64.0 million during the years ended December 31, 2022, 2021 and 2020, respectively.

As of December 31, 2022, the Company had net operating loss carryforwards of approximately \$2.4 billion and \$1.5 billion available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. Of the \$2.4 billion, \$285.0 million will begin to expire in 2030 while \$2.1 billion have no expiration date. The state net operating loss carryforwards will begin to expire in 2030.

As of December 31, 2022, the Company had research and development credit carryforwards of approximately \$79.9 million and \$32.2 million available to reduce our future tax liability, if any, for federal and state income tax purposes, respectively. The federal credit carryforwards begin to expire in 2030. California credit carryforwards have no expiration date.

Internal Revenue Code ("IRC") section 382 places a limitation (the "Section 382 limitation" or "annual limitation") on the amount of taxable income that can be offset by net operating loss carryforwards after a change in control (generally greater than 50% change in ownership) of a loss corporation. Similar provisions exist for states. In addition, and as a result of the acquisitions of Good Start Genetics and CombiMatrix in 2017, acquisitions of Singular Bio, Jungla, and Clear Genetics in 2019, acquisitions of YouScript and ArcherDX in 2020, and acquisitions of One Codex, Genosity, Ciitizen, and Stratify in 2021, tax loss carryforwards from acquired entities are also subject to the Section 382 limitation due to the change in control in the acquired entities in the current year.

In addition, the Company also performed a section 382 analysis in 2022 with respect to our operating loss and credit carryforwards. The Company concluded while an ownership change occurred in 2020 as defined under IRC section 382, none of the Company's net operating loss carryforwards would expire unused solely as a result of annual limitations imposed on the use of the carryforwards under IRC sections 382 and 383.

Our policy with respect to undistributed foreign subsidiaries' earnings is to consider those earnings to be indefinitely reinvested. As a result of the enactment in the Tax Cuts and Job Acts of 2017, if and when funds are actually distributed in the form of dividends or otherwise, we expect minimal tax consequences, except for withholding taxes, which would be applicable in some jurisdiction.

As of December 31, 2022, we had unrecognized tax benefits of \$59.3 million, which primarily relates to research and development credits, \$0.2 million of which would currently affect the Company's effective tax rate if recognized due to the Company's valuation allowance against its deferred tax assets. During the year, the Company benchmarked the reserves of similar tax positions within the industry based on IRS and state audits of comparable companies. Based on its analysis, the Company decreased its unrecognized tax benefits to more closely align with other comparable companies within the industry. As these reserves relate primarily to research and development credits which have a full valuation allowance, such adjustments did not impact the Company's income tax provision. Unrecognized tax benefits are not expected to materially change in the next 12 months.

On November 3, 2022, the Dutch tax authorities published a decree on the Anti-Tax Avoidance Directive 2 ("ATAD2") that relieves the Company of the application of ATAD2 in Netherlands. As a result, the Company has released \$1.7 million of related reserve for the uncertain tax position.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year ended December 31,		
	2022	2021	2020
Unrecognized tax benefits, beginning of period	\$ 46,669	\$ 21,965	\$ 26,985
Gross increases—current period tax positions	14,161	18,165	8,368
Gross increases—prior period tax positions	243	6,539	53
Gross decreases—prior period tax positions	(1,739)	—	(13,441)
Unrecognized tax benefits, end of period	\$ 59,334	\$ 46,669	\$ 21,965

The Company's policy is to include penalties and interest expense related to income taxes as a component of tax expense. The Company has not accrued interest and penalties related to the unrecognized tax benefits reflected in the financial statements for the years ended December 31, 2022, 2021 and 2020.

The Company's major tax jurisdictions are the United States and California. All of the Company's tax years will remain open for examination by the Federal and state tax authorities for three and four years, respectively, from the date of utilization of the net operating loss or research and development credit. The Company does not have any tax audits pending.

13. Net loss per share

The following table presents the calculation of basic and diluted net loss per share (in thousands, except per share data):

	Year ended December 31,		
	2022	2021	2020
Net loss	\$ (3,106,293)	\$ (379,006)	\$ (602,170)
Shares used in computing net loss per share, basic and diluted	235,676	210,946	134,587
Net loss per share, basic and diluted	\$ (13.18)	\$ (1.80)	\$ (4.47)

The following common stock equivalents have been excluded from diluted net loss per share because their inclusion would be anti-dilutive (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Shares of common stock subject to outstanding options	3,113	4,069	6,878
Shares of common stock subject to outstanding warrants	—	29	405
Shares of common stock subject to outstanding RSUs	17,874	9,146	5,590
Shares of common stock subject to outstanding PRSUs	148	737	1,658
Shares of common stock pursuant to ESPP	1,891	425	294
Shares of common stock underlying Series A convertible preferred stock	—	93	125
Shares of common stock subject to Convertible Senior Notes conversion	38,403	38,403	8,371
Total shares of common stock equivalents	61,429	52,902	23,321

14. Geographic information

Revenue by country is determined based on the billing address of the customer and is summarized as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
United States	\$ 457,061	\$ 404,013	\$ 255,680
United Kingdom	9,185	5,485	2,185
Canada	8,779	7,553	4,529
Germany	5,445	8,102	2,299
Rest of world	35,833	35,296	14,905
Total revenue	\$ 516,303	\$ 460,449	\$ 279,598

As of December 31, 2022, 2021 and 2020, our long-lived assets were primarily located in the United States other than operating lease assets representing our right-of-use for leased facilities in Australia, Belgium and Israel.

15. Selected quarterly data (unaudited)

The following tables summarize our quarterly financial information for 2022 and 2021 (in thousands, except per share amounts):

	Three Months Ended			
	March 31, 2022	June 30, 2022	September 30, 2022	December 31, 2022
Revenue	\$ 123,691	\$ 136,622	\$ 133,536	\$ 122,454
Cost of revenue	\$ 97,116	\$ 110,340	\$ 116,956	\$ 92,844
Loss from operations	\$ (213,233)	\$ (2,520,331)	\$ (289,951)	\$ (94,895)
Net loss	\$ (181,859)	\$ (2,523,461)	\$ (301,156)	\$ (99,817)
Net loss per share, basic and diluted ⁽¹⁾	\$ (0.80)	\$ (10.87)	\$ (1.27)	\$ (0.41)

	Three Months Ended			
	March 31, 2021	June 30, 2021	September 30, 2021	December 31, 2021
Revenue	\$ 103,621	\$ 116,312	\$ 114,395	\$ 126,121
Cost of revenue	\$ 75,491	\$ 89,331	\$ 87,741	\$ 96,106
(Loss) income from operations	\$ (112,364)	\$ 128,609	\$ (193,312)	\$ (214,574)
Net (loss) income	\$ (109,492)	\$ 133,786	\$ (198,176)	\$ (205,124)
Net (loss) income per share, basic ⁽¹⁾	\$ (0.56)	\$ 0.66	\$ (0.91)	\$ (0.90)
Net (loss) income per share, diluted ⁽¹⁾	\$ (0.56)	\$ 0.53	\$ (0.91)	\$ (0.90)

⁽¹⁾ Net (loss) income per share is computed independently for each of the quarters presented. Therefore, the sum of quarterly net (loss) income per share information may not equal annual net (loss) income per share.

16. Subsequent events

Payments made on 2020 Term Loan

On February 7, 2023, the Company made a \$53.7 million payment which reduced the principal balance of the 2020 Term Loan by \$50.0 million and included a \$3.0 million prepayment fee, with the remainder attributable to interest. The payment was made by the Company at its sole election.

On February 28, 2023, the Company repaid the remaining principal balance outstanding of \$85.0 million plus outstanding interest of \$1.9 million and a prepayment fee of \$5.1 million.

Debt transactions

On February 28, 2023, the Company announced it has entered into agreements with certain holders of the currently outstanding 2024 Notes. Under the terms of the agreement, Company will (a) exchange approximately \$305.7 million aggregate principal amount of the 2024 Notes for approximately \$275.3 million aggregate principal amount of its new 4.50% Series A Convertible Senior Secured Notes due 2028 ("New 2028 Notes") and \$30.6 million of the Company's common stock and (b) issue and sell \$30.0 million of New 2028 Notes for cash (collectively, the "Transactions"). The Transactions are subject to customary closing conditions and are expected to close on or about March 7, 2023. The New 2028 Notes will be issued pursuant to an indenture.

Under the terms of the agreement, the Company will have the option prior to the maturity date to redeem all or any portion of the principal amount of the New 2028 Notes for cash and warrants to purchase common stock at a ratio as outlined in the indenture. The New 2028 Notes will be convertible at any time prior to the maturity date at the option of the holders, subject to a beneficial ownership cap. In addition, prior to such time that the Company obtains stockholder approval for the issuance of shares of common stock in excess of the limitations imposed by the NYSE rules (the "NYSE Cap"), the holder is prohibited from converting New 2028 Notes into shares of common stock in excess of such NYSE Cap and the Company would instead be required to settle any conversion in cash if the Company is not able to obtain the stockholder approval within the grace period specified in the indenture. The New 2028 Notes will be secured by (i) a security interest in substantially all of the assets of the Company and its material subsidiaries and (ii) a pledge of the equity interests of the Company's direct and indirect material subsidiaries. The indenture includes specific affirmative and restrictive covenants agreed to by the Company.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

ITEM 9A. Controls and Procedures

Evaluation of disclosure controls and procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer) have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation described in Item 9A above that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management’s annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining internal control over our financial reporting. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework (2013 Framework). Based on the assessment using those criteria, our management concluded that, as of December 31, 2022, our internal control over financial reporting was effective. Our independent registered public accounting firm, Ernst & Young LLP, has issued an audit report with respect to our internal control over financial reporting, which appears in Part II, Item 8. of this Annual Report on Form 10-K.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Invitae Corporation

Opinion on Internal Control Over Financial Reporting

We have audited Invitae Corporation's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Invitae Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Invitae Corporation as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and our report dated February 28, 2023 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Mateo, California

February 28, 2023

ITEM 9B. Other Information

None.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

The information required by this item with respect to directors is incorporated by reference from the information under the caption "Election of Directors," contained in our proxy statement to be filed with the Securities and Exchange Commission no later than 120 days from the end of our fiscal year ended December 31, 2022 in connection with the solicitation of proxies for our 2023 Annual Meeting of Stockholders, or the Proxy Statement. Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption "Information about our executive officers" and is incorporated herein by reference.

There have been no material changes to the procedures by which stockholders may recommend nominees to our board of directors.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. To the extent disclosure for delinquent reports is being made, it can be found under the caption "Delinquent Section 16(a) Reports" in the Proxy Statement and is incorporated herein by reference.

Our board of directors has adopted a Code of Business Conduct and Ethics that applies to each of our directors, officers and employees. The Code of Business Conduct and Ethics set forth the basic principles that guide the business conduct of our employees. Our board of directors has also adopted a Code of Ethics for Senior Financial Officers applicable to our Chief Executive Officer and Chief Financial Officer as well as other key management employees addressing ethical issues. The Code of Business Conduct and Ethics and the Code of Ethics for Senior Financial Officers are each posted on our website www.invitae.com. The Code of Business Conduct and Ethics and the Code of Ethics for Senior Financial Officers can only be amended by the approval of a majority of our board of directors. Any waiver to the Code of Business Conduct and Ethics for an executive officer or director or any waiver of the Code of Ethics for Senior Financial Officers may only be granted by our board of directors or our nominating and corporate governance committee and must be timely disclosed as required by applicable law. We have implemented whistleblower procedures that establish formal protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures will be communicated promptly to our audit committee. Stockholders may request a free copy of our Code of Business Conduct and Ethics and Code of Ethics for Senior Financial Officers by contacting Invitae Corporation, Attention: Chief Financial Officer, 1400 16th Street, San Francisco, California 94103. None of the materials on, or accessible through, our website is part of this report or incorporated by reference herein.

To date, there have been no waivers under our Code of Business Conduct and Ethics or Code of Ethics for Senior Financial Officers. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics or Code of Ethics for Senior Financial Officers or waivers of such codes granted to executive officers and directors on our website at www.invitae.com within four business days following the date of such amendment or waiver.

Our board of directors has appointed an Audit Committee, comprised of Christine M. Gorjanc, Geoffrey S. Crouse, Kimber D. Lockhart and William H. Osborne. The board of directors has determined that each of Ms. Gorjanc and Mr. Crouse qualifies as an "audit committee financial expert" under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an "independent director" under the current rules of the New York Stock Exchange and Securities and Exchange Commission rules and regulations.

ITEM 11. Executive Compensation

The information required by this item is incorporated by reference from the information under the captions "Director Compensation," "Compensation Committee Interlocks and Insider Participation" and "Executive Compensation" contained in the Proxy Statement.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference to the disclosure appearing under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation—Equity Compensation Plan Information" contained in the Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference from the information under the captions "Certain Relationships and Related Transactions," "Corporate Governance" and "Director Independence" contained in the Proxy Statement.

ITEM 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference from the information under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm" contained in the Proxy Statement.

PART IV

ITEM 15. Exhibit and Financial Statement Schedules

- (a) Documents filed as part of this report
1. *Financial Statements*: Reference is made to the Index to Financial Statements of Invitae Corporation included in Item 8. of Part II hereof.
 2. *Financial Statement Schedules*: All schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto.
 3. *Exhibits*: See Item 15(b) below. Each management contract or compensating plan or arrangement required to be filed has been identified.
- (b) Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
2.1@	Agreement and Plan of Merger and Plan of Reorganization, dated as of June 21, 2020, by and among Invitae Corporation, Apollo Merger Sub A Inc., Apollo Merger Sub B LLC, ArcherDX, Inc. and Kyle Lefkoff, solely in his capacity as holders' representative.	8-K	2.1	6/24/2020	
2.2@^	Unit Purchase Agreement, dated as of March 10, 2020, by and among Invitae Corporation, David Colaizzi, Chris Howlett, Anthony Muhlenkamp, Gerald Schneider, and Matt Lehrian.	10-Q	2.2	8/4/2020	
3.1	Restated Certificate of Incorporation.	8-K	3.1	2/23/2015	
3.1.1	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Invitae Corporation.	8-K	3.1	8/1/2017	
3.2	Amended and Restated Bylaws.	8-K	3.1	3/23/2021	
4.1	Form of Common Stock Certificate.	10-K	4.1	2/26/2021	
4.2	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.				X
4.3	Indenture, dated as of September 10, 2019, between Invitae Corporation and U.S. Bank National Association, as trustee (including form of Note).	8-K	4.1	9/11/2019	
4.4	Indenture, dated as of April 8, 2021, between Invitae Corporation and U.S. Bank National Association (including form of Note).	8-K	4.1	4/8/2021	
4.5	Amended and Restated Registration Rights Agreement, dated as of July 31, 2017.	8-K	10.4	8/1/2017	
4.6@	Registration Rights Agreement, dated as of October 2, 2020, by and among Invitae Corporation and the investors party thereto.	8-K	10.2	10/5/2020	
10.1#	Form of Indemnification Agreement between Invitae Corporation and its officers and directors.	S-1 (File No. 333-201433)	10.1	1/9/2015	
10.2	Lease Agreement dated as of September 2, 2015 by and between Invitae Corporation and 1400 16th Street LLC.	8-K	10.1	9/4/2015	
10.3	Lease Agreement, dated as of April 20, 2021, by and between Invitae Corporation and APB Owned LLC.	8-K	10.1	4/23/2021	
10.4@^	Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent.	8-K	10.3	10/5/2020	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
10.5	Amendment No. 1, dated as of April 3, 2021, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent, to Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent.	8-K	10.2	4/5/2021	
10.6	Amendment No. 2, dated as of September 20, 2021, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent, to Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent.	10-Q	10.1	11/9/2021	
10.7 [#]	Invitae Corporation 2015 Stock Incentive Plan, as amended and restated as of August 31, 2021.	10-Q	10.3	11/9/2021	
10.8 [#]	Form of Notice of Stock Option Grant and Non-Qualified Stock Option Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.	S-1 (File No. 333-201433)	10.6	2/11/2015	
10.9 [#]	Form of Notice of Restricted Stock Award and Restricted Stock Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.	S-1 (File No. 333-201433)	10.7	2/11/2015	
10.10 [#]	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.	8-K	10.1	8/6/2015	
10.11 [#]	Form of Notice of Time-Based Restricted Stock Unit Award and Time-Based Restricted Stock Unit Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan (Inducement).	10-Q	10.2	8/6/2019	
10.12 ^{#A}	Form of Notice of Performance-Based Restricted Stock Unit Award and Performance-Based Restricted Stock Unit Agreement for awards under the Invitae Corporation 2015 Stock Incentive Plan (Inducement).	10-Q	10.3	8/6/2019	
10.13 [#]	Form of Global Restricted Stock Unit Agreement under the Invitae Corporation 2015 Stock Incentive Plan.	10-Q	10.4	11/9/2021	
10.14 [#]	Invitae Corporation Employee Stock Purchase Plan, as amended and restated as of October 14, 2021.	10-Q	10.2	11/9/2021	
10.15 [#]	ArcherDX, Inc. 2015 Equity Incentive Plan, as amended, and forms of agreements thereunder.	10-K	10.21	2/26/2021	
10.16 [#]	Stratify Genomics Inc. 2018 Equity Incentive Plan, as amended by Amendment No. 1 and Amendment No. 2.	10-K	10.16	3/1/2022	
10.17	Form of Warrant to Purchase Common Stock between Oxford Capital, LLC and Invitae Corporation.	10-K	10.14	3/16/2017	
10.18	Sales Agreement, dated May 4, 2021, between Invitae Corporation and Cowen and Company, LLC.	8-K	1.1	5/4/2021	
10.19 [#]	Offer Letter, dated as of June 1, 2020, by and between Invitae Corporation and Kenneth D. Knight.	8-K	10.1	6/26/2020	
10.20 [#]	Offer Letter, dated as of May 19, 2021, by and between Invitae Corporation and Roxi Wen.	8-K	10.1	6/11/2021	
10.21 [#]	Change of Control and Severance Agreement, dated as of April 23, 2021, by and between Invitae Corporation and Sean George.	10-Q	10.5	8/9/2021	
10.22 [#]	Form of Change of Control and Severance Agreement, between Invitae Corporation and certain officers.	10-Q	10.6	8/9/2021	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
10.23 [@]	Support Agreement, dated as of September 23, 2020, by and among Invitae Corporation and certain securityholders of ArcherDX, Inc.	8-K	10.4	10/5/2020	
10.24	Investment Agreement, dated as of April 3, 2021, by and among Invitae Corporation and parties listed therein (including form of Indenture relating to 1.50% Convertible Senior Notes due 2028).	8-K	10.1	4/5/2021	
10.25 [#]	Change of Control and Severance Agreement, dated July 18, 2022, by and between Invitae Corporation and Kenneth D. Knight.	10-Q	10.1	11/8/2022	
10.26 [#]	Transition and Separation Agreement, dated as of July 17, 2022, by and between Invitae Corporation and Sean George.	10-Q	10.2	11/8/2022	
21.1	List of Subsidiaries.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (contained on the signature page to this Form 10-K).				X
31.1	Principal Executive Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Principal Financial Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1 [*]	Principal Executive Officer's Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).				X
32.2 [*]	Principal Financial Officer's Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).				X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase				X
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document and included as Exhibit 101).				

Indicates management contract or compensatory plan or arrangement.

@ The schedules and exhibits to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

^ Portions of this exhibit have been redacted in accordance with Item 601(b)(2)(ii) and Item 601(b)(10)(iv) of Regulation S-K.

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Exchange Act or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the Company specifically incorporates it by reference.

(c) Financial Statement Schedules: Reference is made to Item 15(a)(2) above.

ITEM 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INVITAE CORPORATION

By: _____

/s/ Kenneth D. Knight

Kenneth D. Knight
Chief Executive Officer
Principal Executive Officer

Date: February 28, 2023

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kenneth D. Knight and Yafei (Roxi) Wen, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons, on behalf of the registrant on the dates and the capacities indicated.

Signature	Title	Date
<u>/s/ Kenneth D. Knight</u> Kenneth D. Knight	Chief Executive Officer (Principal Executive Officer) and Director	February 28, 2023
<u>/s/ Yafei (Roxi) Wen</u> Yafei (Roxi) Wen	Chief Financial Officer (Principal Financial Officer)	February 28, 2023
<u>/s/ Robert F. Werner</u> Robert F. Werner	Chief Accounting Officer (Principal Accounting Officer)	February 28, 2023
<u>/s/ Randal W. Scott, Ph.D.</u> Randal W. Scott, Ph.D.	Chair of the Board and Director	February 28, 2023
<u>/s/ Eric Aguiar, M.D.</u> Eric Aguiar, M.D.	Director	February 28, 2023
<u>/s/ Geoffrey S. Crouse</u> Geoffrey S. Crouse	Director	February 28, 2023
<u>/s/ Christine M. Gorjanc</u> Christine M. Gorjanc	Director	February 28, 2023
<u>/s/ Kimber D. Lockhart</u> Kimber D. Lockhart	Director	February 28, 2023
<u>/s/ Chitra Nayak</u> Chitra Nayak	Director	February 28, 2023
<u>/s/ William H. Osborne</u> William H. Osborne	Director	February 28, 2023

EXHIBIT 5

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2023

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File No. 001-36847



Invitae Corporation

(Exact name of the registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

27-1701898
(I.R.S. Employer
Identification No.)

1400 16th Street, San Francisco, California 94103

(Address of principal executive offices, Zip Code)

(415) 374-7782

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	New York Stock Exchange

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of shares of the registrant's common stock outstanding as of May 5, 2023 was 260,674,728.

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PART I — Financial Information

ITEM 1. Condensed Consolidated Financial Statements

INVITAE CORPORATION
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 161,197	\$ 257,489
Marketable securities	217,501	289,611
Accounts receivable	85,592	96,148
Inventory	19,070	30,386
Prepaid expenses and other current assets	20,908	19,496
Total current assets	504,268	693,130
Property and equipment, net	95,445	108,723
Operating lease assets	78,051	106,563
Restricted cash	10,034	10,030
Intangible assets, net	981,888	1,012,549
Other assets	21,977	23,121
Total assets	\$ 1,691,663	\$ 1,954,116
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	\$ 11,903	\$ 13,984
Accrued liabilities	85,131	74,388
Operating lease obligations	16,374	14,600
Finance lease obligations	4,870	5,121
Convertible senior secured notes, current portion (at fair value)	71,902	—
Total current liabilities	190,180	108,093
Operating lease obligations, net of current portion	143,744	134,386
Finance lease obligations, net of current portion	2,529	3,780
Debt	—	122,333
Convertible senior notes, net	1,169,374	1,470,783
Convertible senior secured notes, net of current portion (at fair value)	211,036	—
Deferred tax liability	7,130	8,130
Other long-term liabilities	4,326	4,775
Total liabilities	1,728,319	1,852,280
Commitments and contingencies (Note 7)		
Stockholders' (deficit) equity:		
Common stock	26	25
Accumulated other comprehensive loss	(108)	(80)
Additional paid-in capital	4,984,750	4,931,032
Accumulated deficit	(5,021,324)	(4,829,141)
Total stockholders' (deficit) equity	(36,656)	101,836
Total liabilities and stockholders' (deficit) equity	\$ 1,691,663	\$ 1,954,116

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenue:		
Test revenue	\$ 112,623	\$ 119,497
Other revenue	4,733	4,194
Total revenue	<u>117,356</u>	<u>123,691</u>
Operating expenses:		
Cost of revenue	88,442	97,116
Research and development	61,978	128,236
Selling and marketing	44,510	60,144
General and administrative	45,241	51,428
Restructuring and other costs	52,556	—
Total operating expenses	<u>292,727</u>	<u>336,924</u>
Loss from operations	(175,371)	(213,233)
Other (expense) income, net:		
Loss on extinguishment of debt, net	(10,822)	—
Debt issuance costs	(19,859)	—
Change in fair value of convertible senior secured notes	18,304	—
Change in fair value of acquisition-related liabilities	218	10,003
Other income, net	5,883	436
Total other (expense) income, net	<u>(6,276)</u>	<u>10,439</u>
Interest expense	(11,496)	(13,985)
Net loss before taxes	<u>(193,143)</u>	<u>(216,779)</u>
Income tax benefit	960	34,920
Net loss	<u>\$ (192,183)</u>	<u>\$ (181,859)</u>
Net loss per share, basic and diluted	<u>\$ (0.77)</u>	<u>\$ (0.80)</u>
Shares used in computing net loss per share, basic and diluted	<u>249,907</u>	<u>228,470</u>

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION
Condensed Consolidated Statements of Comprehensive Loss
(in thousands)
(unaudited)

	<u>Three Months Ended March 31,</u>	
	<u>2023</u>	<u>2022</u>
Net loss	\$ (192,183)	\$ (181,859)
Other comprehensive income (loss):		
Unrealized income (loss) on available-for-sale marketable securities, net of tax	143	(778)
Changes in fair value attributable to instrument-specific credit risk of convertible senior secured notes measured at fair value, net of tax	(171)	—
Comprehensive loss	<u>\$ (192,211)</u>	<u>\$ (182,637)</u>

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION
Condensed Consolidated Statements of Stockholders' (Deficit) Equity
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2023	2022
Common stock:		
Balance, beginning of period	\$ 25	\$ 23
Common stock issued	1	—
Balance, end of period	<u>26</u>	<u>23</u>
Accumulated other comprehensive loss:		
Balance, beginning of period	(80)	(7)
Unrealized income (loss) on available-for-sale marketable securities, net of tax	143	(778)
Changes in fair value attributable to instrument-specific credit risk of convertible senior secured notes measured at fair value, net of tax	(171)	—
Balance, end of period	<u>(108)</u>	<u>(785)</u>
Additional paid-in capital:		
Balance, beginning of period	4,931,032	4,701,230
Common stock issued in connection with the exchange of convertible senior notes due 2024	23,461	—
Common stock issued on exercise of stock options, net	1	425
Common stock and equity awards issued pursuant to acquisitions	1,063	1,660
Stock-based compensation expense	29,193	46,087
Balance, end of period	<u>4,984,750</u>	<u>4,749,402</u>
Accumulated deficit:		
Balance, beginning of period	(4,829,141)	(1,722,848)
Net loss	(192,183)	(181,859)
Balance, end of period	<u>(5,021,324)</u>	<u>(1,904,707)</u>
Total stockholders' (deficit) equity	<u>\$ (36,656)</u>	<u>\$ 2,843,933</u>

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (192,183)	\$ (181,859)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairments and losses on disposals of long-lived assets, net	50,354	—
Depreciation and amortization	34,963	27,100
Stock-based compensation	29,193	46,822
Amortization of debt discount and issuance costs	3,022	3,883
Loss on extinguishment of debt, net	10,822	—
Debt issuance costs	19,859	—
Change in fair value of convertible senior secured notes	(18,304)	—
Remeasurements of liabilities associated with business combinations	(218)	(10,003)
Benefit from income taxes	(960)	(34,920)
Post-combination expense for acceleration of unvested equity and deferred stock compensation	830	1,660
Amortization of premiums and discounts on investment securities	(2,949)	570
Non-cash lease expense	3,111	1,286
Other	824	674
Changes in operating assets and liabilities, net of businesses acquired:		
Accounts receivable	10,556	(14,172)
Inventory	11,316	(9,941)
Prepaid expenses and other current assets	(1,412)	1,654
Other assets	163	(1,984)
Accounts payable	(1,942)	22,863
Accrued expenses and other long-term liabilities	8,557	(1,176)
Net cash used in operating activities	(34,398)	(147,543)
Cash flows from investing activities:		
Purchases of marketable securities	(126,053)	(550,541)
Proceeds from maturities of marketable securities	201,255	121,933
Purchases of property and equipment	(1,324)	(20,848)
Net cash provided by (used in) investing activities	73,878	(449,456)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	1	425
Proceeds from issuance of Series B convertible senior secured notes due 2028	30,000	—
Payments for debt issuance costs and prepayment fees	(28,014)	—
Repayment of debt	(135,000)	—
Finance lease principal payments	(1,289)	(1,330)
Settlement of acquisition obligations	(1,466)	(15)
Net cash used in financing activities	(135,768)	(920)
Net decrease in cash, cash equivalents and restricted cash	(96,288)	(597,919)
Cash, cash equivalents and restricted cash at beginning of period	267,519	933,525
Cash, cash equivalents and restricted cash at end of period	\$ 171,231	\$ 335,606
Supplemental cash flow information of non-cash investing and financing activities:		
Equipment acquired through finance leases	\$ —	\$ 4,472
Purchases of property and equipment in accounts payable and accrued liabilities	\$ 579	\$ 11,675
Common stock issued for acquisition of businesses	\$ 233	\$ —
Exchange of convertible senior notes due 2024	\$ (302,941)	\$ —
Exchange for convertible senior secured notes due 2028	\$ 301,071	\$ —

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Notes to Condensed Consolidated Financial Statements

1. Organization and description of business

Invitae Corporation ("Invitae," "the Company," "we," "us," and "our") was incorporated in the State of Delaware on January 13, 2010, as Locus Development, Inc. and we changed our name to Invitae Corporation in 2012. We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, precision oncology, women's health, rare diseases and pharmacogenomics. To augment our portfolio and realize our mission, we have previously acquired multiple assets and businesses that further expanded our test menu and suite of digital health and offerings and accelerated our entry into key genomics markets. We are building a platform to harness genetics to diagnose more patients correctly and earlier, while enabling our strategic partners to bring therapies to market faster. Invitae operates in one segment.

Strategic realignment

On July 18, 2022, the Company initiated a strategic realignment of our operations and began implementing cost reduction programs to prioritize its core genetic testing and digital health and data platforms, which was approved by the board of directors of the Company on July 16, 2022. See Note 10, "Restructuring and other costs" for additional information regarding our strategic realignment.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2022. The results for the three months ended March 31, 2023 are not necessarily indicative of the results expected for the full fiscal year or any other periods.

2. Summary of significant accounting policies

Principles of consolidation

Our unaudited condensed consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. We base these estimates on current facts, historical and anticipated results, trends and various other assumptions that we believe are reasonable under the circumstances, including assumptions as to future events. Actual results could differ materially from those judgments, estimates and assumptions. We evaluate our estimates on an ongoing basis.

Concentrations of credit risk and other risks and uncertainties

Financial instruments that potentially subject us to a concentration of credit risk consist of cash, cash equivalents, restricted cash, marketable securities and accounts receivable. Our cash and cash equivalents are primarily held by financial institutions in the United States. Such deposits may exceed federally insured limits.

Cash, cash equivalents and restricted cash

Cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets are reconciled to the amounts reported in the condensed consolidated statements of cash flows as follows (in thousands):

	<u>March 31, 2023</u>	<u>March 31, 2022</u>
Cash and cash equivalents	\$ 161,197	\$ 325,331
Restricted cash	10,034	10,275
Total cash, cash equivalents and restricted cash	<u>\$ 171,231</u>	<u>\$ 335,606</u>

Fair value of financial instruments

Our financial instruments consist principally of cash and cash equivalents, marketable securities, accounts receivable, accounts payable, accrued liabilities, operating and finance leases obligations, liabilities associated with business combinations, and convertible senior notes. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued and other current liabilities approximate their current fair value due to the relatively short-term nature of these accounts. Based on borrowing rates available to us, the carrying value of our operating and finance leases approximates their fair values. Liabilities associated with business combinations and the convertible senior secured notes due 2028 are recorded at their estimated fair value.

Fair value option election

The fair value option provides an election that allows an entity to irrevocably elect to record certain financial assets and liabilities at fair value on an instrument-by-instrument basis at initial recognition. We have elected to apply the fair value option to our 4.50% Series A and B convertible senior secured notes due 2028 (collectively, the "Senior Secured 2028 Notes") and stock payable liabilities resulting from business combinations.

The convertible senior secured notes accounted for under the fair value option election pursuant to Accounting Standards Codification ("ASC") 825, *Financial Instruments*, are each a debt host financial instrument containing embedded features which would otherwise be required to be bifurcated from the debt-host and recognized as separate derivative liabilities subject to initial and recurring estimated fair value measurements under ASC 815, *Derivatives and Hedging*. Notwithstanding, ASC 825 provides for the fair value option election, to the extent not otherwise prohibited by ASC 825, to be afforded to financial instruments. When the fair value option election is applied to financial liabilities, bifurcation of an embedded derivative is not required, and the financial liability is initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis as of each reporting period date. The estimated fair value adjustment related to the portion of the change in fair value attributed to a change in the instrument-specific credit risk is recognized as a component of other comprehensive loss, with the remaining amount of the fair value adjustment recognized in other (expense) income, net in our condensed consolidated statements of operations. We have elected to present the component related to accrued interest in the change in fair value of the Senior Secured 2028 Notes.

In circumstances where an acquisition involves certain indemnification hold-backs that are settled in shares of our common stock, we recognize a stock payable liability based upon the number of shares that are issuable to the sellers and the quoted closing price of our common stock as of the reporting date. The number of shares that will ultimately be issued is subject to adjustment for indemnified claims that existed as of the closing date for each acquisition. We remeasure this liability each reporting period and record changes in the fair value related to stock payable liabilities in other income (expense), net in our condensed consolidated statements of operations.

Restructuring and other costs

Restructuring and other costs are comprised of employee severance and benefits, asset impairments and losses on asset disposals, and other costs primarily related to implementing our strategic realignment. Employee severance and benefit costs are comprised of severance, other termination benefit costs, and stock-based compensation expense for the acceleration of stock awards related to workforce reductions. We recognize costs and liabilities associated with exit and disposal activities in accordance with ASC 420, *Exit and Disposal Cost Obligations*, and other costs and liabilities associated with nonretirement postemployment benefits in accordance with ASC 712, *Nonretirement Postemployment Benefits*. Liabilities are based on the estimate of fair value in the period the liabilities are incurred, with subsequent changes to the liability recognized as adjustments in the period of change. We recognize losses on asset disposals in accordance with ASC 360, *Impairment or Disposal of Long-*

Lived Assets. Restructuring and other costs are recognized as an operating expense within the condensed consolidated statements of operations and related liabilities are recorded within accrued liabilities in the condensed consolidated balance sheets.

Recent accounting pronouncements

We evaluate all Accounting Standards Updates (“ASUs”) issued by the Financial Accounting Standards Board (the “FASB”) for consideration of their applicability. ASUs not included in the disclosures in this report were assessed and determined to be either not applicable or are not expected to have a material impact on our condensed consolidated financial statements.

Recently adopted accounting pronouncements

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (“Topic 805”): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*. The amendments of this ASU require entities to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC 606, *Revenue from Contracts with Customers*. The Company adopted the amendments in this update on January 1, 2023 with no impact to our consolidated financial statements at the date of adoption. The amendments will be applied prospectively to future business combinations.

3. Revenue, accounts receivable and deferred revenue

Test revenue is generated from sales of diagnostic tests and precision oncology products to two groups of customers: patients, consideration for which may be paid directly by the patients or the patients' insurance carriers, and institutions (e.g., hospitals, clinics, medical centers and biopharmaceutical partners). Amounts billed and collected, and the timing of collections, vary based on the type of customer and the corresponding payer, including the patients' insurance carriers that are paying on behalf of the customer. Data and service revenue consists principally of revenue recognized for the performance of activities outlined in biopharmaceutical development contracts and other collaboration and genome network agreements.

The following tables present disaggregated revenue by customer and product offering by category (in thousands):

Product:	Patient			Institution	Three Months Ended March 31, 2023
	Insurance	Direct			
Oncology	\$ 50,615	\$ 1,705	\$ 7,986	\$ 60,306	
Women's health	20,210	3,412	1,259	24,881	
Rare diseases	11,427	2,389	6,316	20,132	
Data/services	—	—	12,037	12,037	
Total revenue	\$ 82,252	\$ 7,506	\$ 27,598	\$ 117,356	

Product:	Patient			Institution	Three Months Ended March 31, 2022
	Insurance	Direct			
Oncology	\$ 48,538	\$ 3,436	\$ 20,201	\$ 72,175	
Women's health	16,765	6,004	2,022	24,791	
Rare diseases	6,601	2,717	6,265	15,583	
Data/services	—	—	11,142	11,142	
Total revenue	\$ 71,904	\$ 12,157	\$ 39,630	\$ 123,691	

We recognize revenue related to billings based on estimates of the amount that will ultimately be realized. Cash collections for certain tests delivered may differ from rates originally estimated. In subsequent periods, we update our estimate of the amounts recognized for previously delivered tests resulting in the following (decreases) increases to revenue and (decreases) increases to our net (loss) income from operations and basic and diluted net (loss) income per share (in millions, except per share data):

	Three Months Ended March 31,	
	2023	2022
Revenue	\$ (3.0)	\$ 1.1
(Loss) income from operations	\$ (3.0)	\$ 1.1
Net (loss) income per share, basic and diluted	\$ (0.01)	\$ 0.00

Accounts receivable

The majority of our accounts receivable represents amounts billed to customers for test and data and service activities, and estimated amounts to be collected from patients' insurance carriers for test services.

We record a contract asset for services delivered under certain biopharmaceutical contracts, which are unbilled as of the end of the period. The contract receivable was \$1.1 million and \$1.3 million as of March 31, 2023 and December 31, 2022, respectively, and was included in prepaid expenses and other current assets in the condensed consolidated balance sheets.

Deferred revenue

We record a contract liability when cash payments are received or due in advance of our performance related to one or more performance obligations. The deferred revenue balance primarily consists of advanced billings for biopharmaceutical development services, including billings at the initiation of performance-based milestones, and recognized as revenue in the applicable future period when the revenue is earned. Also included are prepayments related to our consumer direct channel. We recognized revenue of \$2.1 million from deferred revenue during the three months ended March 31, 2023. The current contract liability was \$5.7 million and \$4.8 million as of March 31, 2023 and December 31, 2022, respectively, which was included in accrued liabilities in the condensed consolidated balance sheets. The long-term contract liability was \$36 thousand and \$0.1 million at March 31, 2023 and December 31, 2022, respectively, and was included in other long-term liabilities in the condensed consolidated balance sheets.

Refund liability

As part of our strategic realignment, we terminated early or changed the scope of several companion diagnostic development contracts with milestones in progress. Upon termination, we recorded a refund liability related to the remaining outstanding performance-based milestones. During the three months ended March 31, 2023, we recorded settlement activity associated with the early termination of a companion diagnostic contract. The refund liability was \$2.5 million and \$4.7 million as of March 31, 2023 and December 31, 2022, respectively, which was included in accrued liabilities in the condensed consolidated balance sheets.

Performance obligations

Test and other revenue are generally recognized upon completion of our performance obligation when or as control of the promised good or service is transferred to the customer, which is typically a test report, or upon shipment of our precision oncology products or other contractually defined milestone(s). The Company has applied the practical expedient in relation to information about our remaining performance obligations, as we have a right to consideration from a customer in an amount that corresponds directly with the value to the customer of the Company's performance completed to date. Most remaining performance obligations are primarily related to Personalized Cancer Monitoring ("PCM") services included in test revenue in our condensed consolidated statement of operations and are generally satisfied over one to six months.

4. Intangible assets

The following table presents details of our acquired intangible assets as of March 31, 2023 (in thousands):

	March 31, 2023				Weighted-Average Useful Life (In Years)
	Cost	Accumulated Amortization	Asset Disposals	Net	
Customer relationships	\$ 40,928	\$ (18,577)	\$ —	\$ 22,351	10.8
Developed technology	1,138,702	(193,796)	(2,051)	942,855	10.8
Trade name	21,072	(4,390)	—	16,682	12.0
	<u>\$ 1,200,702</u>	<u>\$ (216,763)</u>	<u>\$ (2,051)</u>	<u>\$ 981,888</u>	10.8

The following table presents details of our acquired intangible assets as of December 31, 2022 (in thousands):

	December 31, 2022				Weighted-Average Useful Life (In Years)
	Cost	Accumulated Amortization	Asset Disposals	Net	
Customer relationships	\$ 41,515	\$ (17,675)	\$ (359)	\$ 23,481	10.8
Developed technology	1,174,506	(183,133)	(19,426)	971,947	10.8
Non-compete agreement	286	(286)	—	—	—
Trade name	21,085	(3,964)	—	17,121	12.0
Patent assets and licenses	495	(156)	(339)	—	—
Right to develop new technology	19,359	(2,474)	(16,885)	—	—
	<u>\$ 1,257,246</u>	<u>\$ (207,688)</u>	<u>\$ (37,009)</u>	<u>\$ 1,012,549</u>	10.8

Acquisition-related intangibles included in the above tables are generally finite-lived and are carried at cost less accumulated amortization. Customer relationships are being amortized on an accelerated basis in proportion to estimated cash flows. All other finite-lived acquisition-related intangibles are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized. Amortization expense was \$28.6 million and \$20.2 million for the three months ended March 31, 2023 and 2022, respectively. Amortization expense is recorded in cost of revenue, research and development, and selling and marketing expense in our condensed consolidated statements of operations.

In March 2023, we decided to cease development of acquired technology focused on informing clinical decisions as management continued to evaluate its investments in development. During the three months ended March 31, 2023, we wrote-off the remaining carrying value of the related developed technology intangible asset of \$2.1 million and recognized \$1.0 million for related contractual obligations, which are included in restructuring and other costs in the condensed consolidated statements of operations. See Note 10, "Restructuring and other costs" for additional information.

The following table summarizes our estimated future amortization expense of intangible assets with finite lives as of March 31, 2023 (in thousands):

2023 (remainder of year)	\$ 85,559
2024	113,800
2025	112,046
2026	112,012
2027	111,346
Thereafter	447,125
Total estimated future amortization expense	<u>\$ 981,888</u>

5. Balance sheet components

Inventory

Inventory consisted of the following (in thousands):

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
Raw materials	\$ 18,913	\$ 29,992
Work in progress	157	382
Finished goods	—	12
Total inventory	<u>\$ 19,070</u>	<u>\$ 30,386</u>

Property and equipment, net

Property and equipment consisted of the following (in thousands):

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
Leasehold improvements	\$ 72,184	\$ 73,095
Laboratory equipment	62,267	67,261
Computer equipment	13,368	13,511
Furniture and fixtures	1,364	1,427
Construction-in-progress	14,186	21,006
Other	5,955	2,996
Total property and equipment, gross	169,324	179,296
Accumulated depreciation	(73,879)	(70,573)
Total property and equipment, net	<u>\$ 95,445</u>	<u>\$ 108,723</u>

Depreciation expense was \$5.4 million and \$5.6 million for the three months ended March 31, 2023 and 2022, respectively.

During the first quarter of 2023, we decided to exit certain leased premises and we recognized a loss on disposal of property and equipment, net of \$8.5 million during the three months ended March 31, 2023 for related lab equipment and leasehold improvements, which is included in restructuring and other costs in our condensed consolidated statement of operations. See Note 7, "Commitments and contingencies" and Note 10, "Restructuring and other costs" for additional information.

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
Accrued compensation and related expenses	\$ 33,424	\$ 25,315
Accrued expenses	32,394	23,628
Compensation and other liabilities associated with business combinations	3,881	5,335
Deferred revenue	5,721	4,814
Accrued interest	62	6,646
Accrued royalties	2,421	3,177
Other accrued liabilities	7,228	5,473
Total accrued liabilities	<u>\$ 85,131</u>	<u>\$ 74,388</u>

6. Fair value measurements

Financial assets and liabilities are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The authoritative guidance establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques is summarized as follows:

Level 1—Observable inputs such as quoted prices (unadjusted) for identical instruments in active markets.

Level 2—Observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-derived valuations whose significant inputs are observable.

Level 3—Unobservable inputs that reflect the reporting entity’s own assumptions.

The following tables set forth the fair value of our financial instruments that were measured at fair value on a recurring basis (in thousands):

	March 31, 2023						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	\$ 169,399	\$ —	\$ —	\$ 169,399	\$ 169,399	\$ —	\$ —
U.S. Treasury notes	33,042	11	—	33,053	33,053	—	—
U.S. government agency securities	184,395	53	—	184,448	—	184,448	—
Total financial assets	<u>\$ 386,836</u>	<u>\$ 64</u>	<u>\$ —</u>	<u>\$ 386,900</u>	<u>\$ 202,452</u>	<u>\$ 184,448</u>	<u>\$ —</u>
Financial liabilities:							
Stock payable liability				\$ 300	\$ —	\$ —	\$ 300
Contingent consideration				25	—	—	25
Convertible senior secured notes				282,938	—	—	282,938
Total financial liabilities				<u>\$ 283,263</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 283,263</u>

	March 31, 2023	
Reported as:		
Cash equivalents	\$	159,365
Restricted cash		10,034
Marketable securities		217,501
Total cash equivalents, restricted cash, and marketable securities	<u>\$</u>	<u>386,900</u>
Convertible senior secured notes, current portion	\$	71,902
Convertible senior secured notes, net of current portion		211,036
Other long-term liabilities		325
Total liabilities	<u>\$</u>	<u>283,263</u>

December 31, 2022

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	\$ 158,931	\$ —	\$ —	\$ 158,931	\$ 158,931	\$ —	\$ —
U.S. Treasury notes	193,685	1	(123)	193,563	193,563	—	—
U.S. government agency securities	96,006	55	(13)	96,048	—	96,048	—
Total financial assets	<u>\$ 448,622</u>	<u>\$ 56</u>	<u>\$ (136)</u>	<u>\$ 448,542</u>	<u>\$ 352,494</u>	<u>\$ 96,048</u>	<u>\$ —</u>
Financial liabilities:							
Stock payable liability				\$ 744	\$ —	\$ —	\$ 744
Contingent consideration				25	—	—	25
Total financial liabilities				<u>\$ 769</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 769</u>

December 31, 2022

Reported as:	
Cash equivalents	\$ 148,901
Restricted cash	10,030
Marketable securities	289,611
Total cash equivalents, restricted cash, and marketable securities	<u>\$ 448,542</u>
Other long-term liabilities	<u>\$ 769</u>

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. Our debt securities of U.S. government agencies are classified as Level 2 as they are valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to benchmark yields, interest rate curves, reported trades, broker/dealer quotes and reference data. At March 31, 2023, the remaining contractual maturities of available-for-sale securities ranged from zero to three months. Interest income generated from our investments was \$2.0 million and \$1.2 million during the three months ended March 31, 2023 and 2022, respectively, which is included in other income, net in the condensed consolidated statements of operations.

The total fair value of investments with unrealized losses at March 31, 2023 was zero. None of the available-for-sale securities held as of March 31, 2023 have been in an unrealized loss position for more than one year. The Company evaluates investments that are in an unrealized loss position for impairment as a result of credit loss. It was determined that no credit losses exist as of March 31, 2023, because the change in market value of those securities has resulted from fluctuations in market interest rates since the time of purchase, rather than a deterioration of the credit worthiness of the issuers. For marketable securities in an unrealized loss position, we assess our intent to sell, or whether it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. We intend to hold our marketable securities to maturity and it is unlikely that they would be sold before their cost bases are recovered. The cost of securities sold is based on the specific identification method.

The following tables include a rollforward of the stock payable liability, contingent consideration, and Senior Secured 2028 Notes classified within Level 3 of the fair value hierarchy (in thousands):

	Stock Payable Liability	Contingent Consideration	Convertible Senior Secured Notes
Fair value at December 31, 2022	\$ 744	\$ 25	\$ —
Issuance of convertible senior secured notes at fair value	—	—	301,071
Changes in fair value	(218)	—	(18,304)
Changes in fair value related to instrument-specific credit risk	—	—	171
Settlements	(226)	—	—
Fair value at March 31, 2023	<u>\$ 300</u>	<u>\$ 25</u>	<u>\$ 282,938</u>

	Stock Payable Liability	Contingent Consideration
Fair value at December 31, 2021	\$ 20,925	\$ 1,875
Change in fair value	(10,003)	154
Fair value at March 31, 2022	<u>\$ 10,922</u>	<u>\$ 2,029</u>

Stock payable liabilities relate to certain indemnification hold-backs resulting from business combinations that are settled in shares of our common stock. We elected to account for these liabilities using the fair value option due to the inherent nature of the liabilities and the changes in value of the underlying shares that will ultimately be issued to settle the liabilities. The estimated fair value of these liabilities is classified as Level 3 and determined based upon the number of shares that are issuable to the sellers and the quoted closing price of our common stock as of the reporting date. The number of shares that will ultimately be issued is subject to adjustment for indemnified claims that existed as of the closing date for each acquisition. Changes in the number of shares issued and share price can significantly affect the estimated fair value of the liabilities. The change in fair value related to stock payable liabilities was income of \$0.2 million and \$10.0 million during the three months ended March 31, 2023 and 2022, respectively, which is recorded in change in fair value of acquisition-related liabilities in the condensed consolidated statements of operations.

Contingent consideration relates to the obligation we may be required to pay in the form of additional shares of our common stock resulting from the acquisition of Genelex in April 2020. The amount of the contingent obligation is dependent upon the achievement of a certain product milestone, at which time we would issue shares of our common stock with a value equal to a portion of the gross revenues actually received by us for a pharmacogenetic product reimbursed through certain payers during an earn-out period of up to four years. The estimated fair value of the contingent consideration is based upon significant inputs not observable in the market and, therefore, represents a Level 3 measurement. The material factors that may impact the fair value of the contingent consideration, and therefore, this liability, are the probabilities and timing of achieving the related milestone, the estimated revenues achieved for a pharmacogenetic product and the discount rate used to estimate the fair value. Significant changes in any of the probabilities of success would result in a significant change in the estimated fair value of the liability. The change in fair value related to contingent consideration recorded to other (expense) income, net was zero and expense of \$0.2 million during the three months ended March 31, 2023 and 2022, respectively.

In March 2023, the Company issued 4.50% Series A convertible senior secured notes due 2028 ("Series A Notes") with an aggregate principal amount of \$275.3 million, and Series B convertible senior secured notes due 2028 (the "Series B Notes") with an aggregate principal amount of \$30.0 million. The Company elected the fair value option to account for the Senior Secured 2028 Notes. We utilize the binomial lattice model, specifically a lattice model to estimate the fair value of the convertible senior secured notes at issuance and subsequent reporting dates. The estimated fair value of the Senior Secured 2028 Notes is determined using Level 3 inputs and assumptions unobservable in the market. This model incorporates the terms and conditions of the Senior Secured 2028 Notes and assumptions related to stock price, expected stock price volatility, risk-free interest rate, market credit spread, and cost of debt. The stock price is based on the publicly traded price of our common stock as of the measurement date. We estimate the volatility of our stock price based on the historical and implied volatilities of our publicly traded common stock. The risk-free interest rate is based on interpolated U.S. Treasury rates, commensurate with a similar term to the Senior Secured 2028 Notes. The most significant assumptions in the binomial lattice model impacting the fair value of the Senior Secured 2028 Notes are (i) the estimated stock price,

(ii) the estimated cost of debt, and (iii) the volatility of our common stock. Significant changes in any of these inputs may result in a significant change in the fair value of the Senior Secured 2028 Notes.

Under the fair value election as prescribed by ASC 825, we will record changes in fair value, inclusive of related accrued interest, through the condensed consolidated statement of operations as a fair value adjustment of the convertible senior secured debt each reporting period, with the portion of the change that results from a change in the instrument-specific credit risk recorded separately in other comprehensive loss, if applicable. The portion of total changes in fair value of debt attributable to changes in instrument-specific credit risk are determined through specific measurement of periodic changes in the risk-free interest rate, credit spread, and cost of debt assumptions. The initial carrying amount of the Senior Secured 2028 Notes, measured at the estimated fair value on the date of issuance, was \$301.1 million. As of March 31, 2023, the estimated fair value was \$282.9 million. During the three months ended March 31, 2023, the corresponding change in fair value of the Senior Secured 2028 Notes was a gain of \$18.3 million, which is included in other (expense) income, net in the condensed consolidated statements of operations. The change in fair value related to instrument-specific credit risk was \$0.2 million, which is included in the condensed consolidated statements of comprehensive loss. See Note 7, "Commitments and contingencies" under the heading "Convertible senior notes—Convertible senior secured notes due 2028" for a description of the Senior Secured 2028 Notes.

Significant inputs into the binomial lattice model as of March 31, 2023 and March 7, 2023 were as follows:

	March 31, 2023	March 7, 2023
Stock price	\$1.35	\$1.65
Conversion price	\$2.58	\$2.58
Volatility	110.0 %	107.5 %
Risk-free interest rate	3.64 %	4.35 %
Credit spread	13.74 %	13.76 %
Cost of debt	17.4 %	18.1 %
Term (years)	4.96	5.02

7. Commitments and contingencies

Leases

The Company has entered into various non-cancellable operating lease agreements for office and laboratory space domestically and internationally. The Company's current leases have remaining terms ranging from approximately 1 to 12 years, some of which include options to extend the leases. The renewal options were not included in the calculation of the operating lease assets and the operating lease liabilities as they are not reasonably certain of being exercised. The security deposits for our operating leases are included in restricted cash in our condensed consolidated balance sheets.

In 2015, we entered into a non-cancelable operating lease agreement for our headquarters and main production facility in San Francisco, California, which commenced in 2016 with an initial lease term extending through 2026. In 2020, we entered into a non-cancelable operating lease agreement for additional office and laboratory space in San Francisco, California, which commenced in 2021 and has an initial lease term extending through 2031. In 2021, we entered into a non-cancelable operating lease agreement for a new laboratory and production facilities in Morrisville, North Carolina, which commenced in the same year with an initial lease term extending through 2035. See the discussion below regarding management's decision to exit the operating leases for additional office and laboratory space in San Francisco, California and a portion of the new laboratory and production facilities in Morrisville, North Carolina and the related impairment in the first quarter of 2023.

We have entered into various finance lease agreements to obtain laboratory equipment. The terms of our finance leases are generally three years and are typically secured by the underlying equipment. The portion of the future payments designated as principal repayment and related interest was classified as a finance lease obligation in our condensed consolidated balance sheets. Finance lease assets are recorded within other assets in our condensed consolidated balance sheets.

During the first quarter of 2023, we decided to exit certain leased premises and actively began looking to sublease certain facilities, including the related leasehold improvements. We determined that the changes in the intended use of these locations represented an indicator of impairment and performed a test of recoverability on March 31, 2023. For operating leases where the carrying values of the asset group were lower than the undiscounted cash flows expected through sublease, we impaired the asset group to their fair value. The fair value

was determined by utilizing the discounted cash flow method under the income approach. The key inputs to this valuation were expected sublease rental income ranging from \$7.6 million to \$35.7 million and a discount rate ranging from 7.0% to 8.0%. This fair value measurement is based on significant inputs not observable in the market and, therefore, represents a Level 3 measurement. During the three months ended March 31, 2023, we recognized an impairment charge of \$37.8 million related to the right-of-use assets and \$2.0 million for the related leasehold improvements, which are included in restructuring and other costs in our condensed consolidated statement of operations.

During the first quarter of 2023, we reassessed certain leases previously impaired as part of the strategic realignment for additional impairment due to the continued decline in market conditions and changes in the ability to sublease the properties. We determined that the changes in market conditions represented an indicator of impairment and performed a test of recoverability on March 31, 2023. For operating leases where the carrying values of the asset group were lower than the undiscounted cash flows expected through sublease, we further impaired the asset group to their fair value. The fair value was determined by utilizing the discounted cash flow method under the income approach. The key inputs to this valuation were expected sublease rental income ranging from \$0.3 million to \$1.9 million and discount rates ranging from 7.50% to 7.75%. This fair value measurement is based on significant inputs not observable in the market and, therefore, represents a Level 3 measurement. During the three months ended March 31, 2023, we recognized an impairment charge of \$2.3 million related to the right-of-use assets, which is included in restructuring and other costs in our consolidated statements of operations.

Sublease income was \$0.4 million during the three months ended March 31, 2023. There was no sublease income for the three months ended March 31, 2022.

Debt financing

In October 2020, we entered into a credit agreement with a financial institution under which we borrowed \$135.0 million (the "2020 Term Loan") concurrent with the closing of the ArcherDX, Inc. ("ArcherDX") acquisition. The 2020 Term Loan is secured by a first priority lien on all of our and our subsidiaries' assets, and is guaranteed by us and our subsidiaries. The 2020 Term Loan bears interest at an annual rate equal to three-month LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75%. If three-month LIBOR can no longer be determined or if the applicable governmental authority ceases to supervise or sanction such rates, then we will endeavor to agree with the administrative agent, an alternate rate of interest that gives due consideration to the then prevailing market convention for determining interest for comparable loans in the United States, provided that until such alternative rate of interest is agreed, the 2020 Term Loan shall bear interest at the *Wall Street Journal* Prime Rate. The three-month LIBOR is expected to be available and representative through June 30, 2023. The 2020 Term Loan will mature on (i) June 1, 2024, if at such time our 2024 Notes (defined below) are outstanding and are due to mature on September 1, 2024 (provided that if, prior to such date, the maturity date of at least 80% of the 2024 Notes is extended to a date that is prior to September 1, 2025, the maturity date for the 2020 Term Loan will be automatically extended to a date that is 90 days prior to such 2024 Notes maturity date as extended), or (ii) otherwise, on June 1, 2025. The full amount of the 2020 Term Loan is due upon maturity. If the 2020 Term Loan is prepaid (whether such prepayment is optional or mandatory), we must pay a prepayment fee of 6% if the prepayment occurs prior to the third anniversary of the closing date or 4% if the prepayment occurs after the third anniversary of the closing date and we must also pay a make-whole fee if the prepayment occurs prior to the second anniversary of the closing date.

The credit agreement contains customary events of default and covenants, including among others, covenants limiting our ability to incur debt, incur liens, undergo a change in control, merge with or acquire other entities, make investments, pay dividends or other distributions to holders of our equity securities, repurchase stock, and dispose of assets, in each case subject to certain customary exceptions. In addition, the credit agreement contains financial covenants that require us to maintain a minimum cash balance and minimum quarterly revenue levels.

Debt discounts, including debt issuance costs, related to the 2020 Term Loan of \$32.8 million were recorded as a direct deduction from the debt liability and are being amortized to interest expense over the term of the 2020 Term Loan. Interest expense related to our debt financings, excluding the impact of our convertible senior notes (defined below), was \$4.1 million and \$5.9 million for the three months ended March 31, 2023 and 2022, respectively.

In February 2023, we repaid, prior to the maturity date, the principal balance outstanding of \$135.0 million plus accrued interest of \$2.6 million. During the three months ended March 31, 2023, we incurred debt extinguishment costs of \$19.3 million related to the repayment, which included the write-off of unamortized debt

issuance costs of \$11.2 million and prepayment fees of \$8.1 million, which are included in loss on extinguishment of debt, net in the condensed consolidated statements of operations.

Convertible senior notes

Convertible senior notes due 2024

In September 2019, we issued, at par value, \$350.0 million aggregate principal amount of 2.00% convertible senior notes due 2024 (the "2024 Notes") in a private offering. The 2024 Notes are our senior unsecured obligations and will mature on September 1, 2024, unless earlier converted, redeemed or repurchased. The 2024 Notes bear cash interest at a rate of 2.0% per year, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on March 1, 2020.

Upon conversion, the 2024 Notes will be convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate for the 2024 Notes is 33.6293 shares of our common stock per \$1,000 principal amount of the 2024 Notes (equivalent to an initial conversion price of approximately \$29.74 per share of common stock).

If we undergo a fundamental change (as defined in the indenture governing the 2024 Notes), the holders of the 2024 Notes may require us to repurchase all or any portion of their 2024 Notes for cash at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased plus accrued and unpaid interest to, but excluding, the redemption date.

The 2024 Notes will be convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding March 1, 2024, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on December 31, 2019 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2024 Notes on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per \$1,000 principal amount of 2024 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (3) if we call any or all of the 2024 Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or (4) upon the occurrence of specified corporate events. On or after March 1, 2024 until the close of business on the business day immediately preceding the maturity date, holders may convert their 2024 Notes at any time, regardless of the foregoing circumstances. Since issuance, these notes were convertible at the option of the holders during the quarters beginning on January 1, 2021 and April 1, 2021 due to the sale price of our common stock during the quarters ended December 31, 2020 and March 31, 2021, respectively. The notes were not convertible during the three months ended March 31, 2023 and there have been no significant conversions in the periods in which they were convertible.

We may redeem for cash all or any portion of the 2024 Notes, at our option, on or after September 6, 2022 and on or before the 30th scheduled trading day immediately before the maturity date if the last reported sale price of the common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

See the discussion below regarding the purchase and exchange agreements with certain holders of the outstanding 2024 Notes. As of March 31, 2023, the outstanding principal balance of the 2024 Note was \$44.3 million.

Convertible senior notes due 2028

In April 2021, we issued, at 99% of par value, \$1,150.0 million aggregate principal amount of 1.5% convertible senior notes due 2028 (the "2028 Notes") in a private offering. The 2028 Notes are our senior unsecured obligations and will mature on April 1, 2028, unless earlier converted, redeemed or repurchased. The 2028 Notes bear cash interest at a rate of 1.5% per year, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on October 1, 2021. Upon conversion, the 2028 Notes will be convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

The 2028 Notes will be convertible at the option of the holder at any time until the second scheduled trading day prior to the maturity date, including in connection with a redemption by us. The 2028 Notes will be convertible into shares of our common stock based on an initial conversion rate of 23.1589 shares of common stock per \$1,000 principal amount of the 2028 Notes (which is equal to an initial conversion price of \$43.18 per share), in each case subject to customary anti-dilution and other adjustments as a result of certain extraordinary transactions. None of the 2028 Notes have been converted to date.

We may not redeem the 2028 Notes prior to April 6, 2025. On or after April 6, 2025, the 2028 Notes will be redeemable by us in the event that the closing sale price of our common stock has been at least 150% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide the redemption notice at a redemption price of 100% of the principal amount of such 2028 Notes, plus accrued and unpaid interest to, but excluding, the redemption date.

With certain exceptions, upon a change of control of the Company or the failure of our common stock to be listed on certain stock exchanges, the holders of the 2028 Notes may require that we repurchase all or part of the principal amount of the Notes at a repurchase price of 100% of the principal amount of the 2028 Notes to be repurchased, plus unpaid interest to, but excluding, the maturity date.

Summary of convertible senior notes

Our 2024 Notes and 2028 Notes (collectively, our "Convertible Senior Notes") consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Outstanding principal	\$ 1,194,269	\$ 1,499,996
Unamortized debt discount and issuance costs	(24,895)	(29,213)
Net carrying amount	<u>\$ 1,169,374</u>	<u>\$ 1,470,783</u>

As of March 31, 2023, the fair value of the 2024 Notes and 2028 Notes was \$38.9 million and \$492.4 million, respectively. The estimated fair value of the 2024 Notes and 2028 Notes, which use Level 2 fair value inputs, was determined based on the estimated or actual bid prices in an over-the-counter market and/or market conditions including the price and volatility of our common stock and comparable company information. We recognized \$7.2 million and \$7.7 million of interest expense related to our Convertible Senior Notes during the three months ended March 31, 2023 and 2022, respectively. Of the interest expense recognized, \$1.5 million and \$1.6 million during the three months ended March 31, 2023 and 2022, respectively, was related to amortization of issuance costs and the remainder was related to contractual interest incurred.

Convertible senior secured notes due 2028

In February 2023, we entered into purchase and exchange agreements with certain holders of the outstanding 2024 Notes. Under the terms of the agreements, we (a) exchanged \$305.7 million aggregate principal amount of 2024 Notes for \$275.3 million aggregate principal amount of Series A Notes and 14,219,859 shares of the Company's common stock and (b) issued and sold \$30.0 million aggregate principal amount of Series B Notes for cash.

The Senior Secured 2028 Notes are our senior secured obligations and will mature on March 15, 2028, unless earlier converted, redeemed or repurchased. The Senior Secured 2028 Notes bear cash interest at a rate of 4.50% per year, payable quarterly in arrears on March 15, June 15, September 15 and December 15 of each year, beginning on June 15, 2023.

Based on the initial conversion price of \$2.58, the Senior Secured 2028 Notes will be initially convertible into an aggregate of 118,316,667 shares of common stock, and after taking into account the maximum number of additional shares issuable in certain circumstances as described in the indenture, an aggregate of 141,979,975 shares of common stock.

At any time prior to the 60th day prior to the maturity date of the Senior Secured 2028 Notes, we have the option to redeem all or any portion of the principal amount of the Senior Secured 2028 Notes for cash equal to the principal amount of the Senior Secured 2028 Notes to be redeemed. Upon redemption of any Senior Secured 2028 Notes, we will (i) issue warrants to purchase shares of common stock, unless the aggregate principal amount of Senior Secured 2028 Notes outstanding represents less than 10% of the aggregate principal amount of Senior Secured 2028 Notes initially issued and certain other conditions are satisfied, and (ii) make a make-whole payment

as determined pursuant to the indenture governing the Senior Secured 2028 Notes, together with accrued and unpaid interest through the redemption date. In addition, in certain circumstances, we may be required to issue additional shares of common stock for any Senior Secured 2028 Notes converted in connection with a notice of optional redemption. The indenture governing the Senior Secured 2028 Notes also provides for the issuance of warrants to purchase shares of common stock in connection with the prepayment of the Senior Secured 2028 Notes upon acceleration of the Senior Secured 2028 Notes following the occurrence of an event of default under the indenture as a result of the failure by the Company to settle any conversion. Any warrants issued will cover the same number of shares of the common stock underlying and at an exercise price equal to the conversion price of the redeemed or prepaid Senior Secured 2028 Notes. The number of shares issuable upon conversion or exercise is subject to customary anti-dilution and other adjustments (as defined in the indenture governing the Senior Secured 2028 Notes).

The Senior Secured 2028 Notes will be convertible at any time prior to the maturity date at the option of the holders, subject to a beneficial ownership cap. In addition, prior to such time that the Company obtains stockholder approval for the issuance of shares of common stock in excess of the limitations imposed by the NYSE rules (the "NYSE Cap"), holders of the Series A Notes are prohibited from converting their notes or exercising any warrants issued in respect of the Series A Notes into shares of common stock in excess of such NYSE Cap and we would instead be required to settle any conversion in cash if we are not able to obtain the stockholder approval prior to September 30, 2023 (the grace period specified in the indenture). The cash settlement amount upon conversion of a Series A Note by a holder prior to stockholder approval is equal to the product of the shares of common stock in excess of the NYSE Cap multiplied by the arithmetic average of the volume weighted average price of our common stock on each of the five consecutive trading days immediately preceding the conversion date. After obtaining stockholder approval, the full amount of the outstanding balance of the Senior Secured 2028 Notes will be convertible into shares of common stock, with no conversion limitations. There can be no assurance that we will be successful in obtaining stockholder approval for the proposal to approve the issuance of shares of common stock pursuant to the conversion of the Senior Secured 2028 Notes or the exercise of any warrants issued in respect to the Senior Secured 2028 Notes in excess of the limitations imposed by the NYSE Cap prior to September 30, 2023. If we fail to obtain stockholder approval, we may not have enough available cash or be able to obtain financing at the time we are required to settle any conversion.

If we undergo a major transaction (as defined in the indenture), holders may require us to repurchase for cash all or part of their Senior Secured 2028 Notes at a purchase price equal to 100% of the principal amount of the Senior Secured 2028 Notes to be repurchased, plus (i) accrued and unpaid interest to, but excluding, the repurchase date and (ii) the make-whole amount as determined pursuant to the indenture governing the Senior Secured 2028 Notes. In addition, at the election of the holders of the Senior Secured 2028 Notes, we may be required to issue additional shares of common stock for any Senior Secured 2028 Notes converted in connection with a major transaction.

The Senior Secured 2028 Notes are guaranteed by our material subsidiaries and secured by (i) a security interest in substantially all of the assets of the Company and its domestic material subsidiaries and (ii) a pledge of the equity interests of the Company's direct and indirect subsidiaries, subject to certain customary exceptions. The indenture contains certain specified events of default, the occurrence of which would entitle the holders of the Senior Secured 2028 Notes to demand repayment of all outstanding principal and accrued interest on the Notes, together with a make-whole payment as determined pursuant to the indenture. The indenture also includes specific affirmative and restrictive covenants agreed to by the Company. In addition, the indenture also contains financial covenants that will require us to maintain revenue in the prior four quarters of not less than \$250.0 million and, starting with the quarter ending March 31, 2025, a minimum liquidity of at least 15% of the amount of our secured indebtedness then outstanding. As of March 31, 2023, we are in compliance with all restrictive and financial covenants.

We elected the fair value option to account for the Senior Secured 2028 Notes, which requires the notes to be accounted for as a single liability initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis as of each reporting date. We have elected not to present the interest expenses separate from the fair value changes of the Senior Secured 2028 Notes. Considering the terms of settlement noted above, we elected the fair value option for the Senior Secured 2028 Notes as we believe it best reflects the underlying economics and also for simplification and cost-benefit considerations of accounting such Senior Secured 2028 Notes at fair value versus bifurcation of the embedded derivatives.

The initial carrying amount of the Senior Secured 2028 Notes, measured at the estimated fair value on the date of issuance, was \$301.1 million. As of March 31, 2023, the estimated fair value of the Senior Secured 2028 Notes was \$282.9 million. The portion of the estimated fair value of Series A Notes for which conversion is subject

to stockholder approval and for which the Company has a cash settlement obligation is classified as a current liability with the remainder classified as a long-term liability in the condensed consolidated balance sheets. The current liability was determined based on the product of the shares of common stock in excess of the NYSE Cap multiplied by the arithmetic average of the volume weighted average price of our common stock on each of the five consecutive trading dates immediately preceding March 31, 2023. The long-term liability represents the portion of the Senior Secured 2028 Notes for which we have the intent and the ability to settle the obligations by issuing shares. During the three months ended March 31, 2023, the corresponding change in fair value of the Senior Secured 2028 Notes was a gain of \$18.3 million, which is included in other (expense) income, net in the condensed consolidated statements of operations. During the three months ended March 31, 2023, the change in fair value related to instrument-specific credit risk was \$0.2 million, which is included in the condensed consolidated statements of comprehensive loss.

In connection with the issuance of the Senior Secured 2028 Notes, we incurred approximately \$19.9 million of debt issuance costs primarily related to legal and consulting fees paid to third parties, which were expensed as incurred during the three months ended March 31, 2023 and included in other (expense) income, net in the condensed consolidated statements of operations.

The exchange of the 2024 Notes for the Senior Secured 2028 Notes was treated as an extinguishment of debt, and we recognized a gain on extinguishment of \$8.5 million representing the difference between the fair value of the Series A Notes immediately prior to the exchange plus the fair value of common shares issued and the carrying amount of the 2024 Notes, which is included in loss on extinguishment of debt, net in the condensed consolidated statements of operations.

Other commitments

In the normal course of business, we enter into various purchase commitments primarily related to service agreements and laboratory supplies. At March 31, 2023, our total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were \$35.6 million.

Guarantees and indemnification

As permitted under Delaware law and in accordance with our bylaws, we indemnify our directors and officers for certain events or occurrences while the officer or director is or was serving in such capacity. The maximum amount of potential future indemnification is unlimited; however, we maintain director and officer liability insurance. This insurance allows the transfer of the risk associated with our exposure and may enable us to recover a portion of any future amounts paid. We believe the fair value of these indemnification agreements is minimal. Accordingly, we did not record any liabilities associated with these indemnification agreements at March 31, 2023 or December 31, 2022.

Contingencies

We are and may from time to time be involved in various legal proceedings and claims arising in the ordinary course of business. Legal proceedings, including litigation, government investigations and enforcement actions could result in material costs, occupy significant management resources and entail civil and criminal penalties, even if we ultimately prevail. If an investigation results in a proceeding against us, an adverse outcome could include us being required to pay treble damages, and incur attorneys' fees, civil or criminal penalties and other adverse actions that could materially and adversely affect our business, financial condition and results of operations. While we believe any such claims are unsubstantiated, and we believe we are in compliance with applicable laws and regulations applicable to our business, the resolution of any such claims could be material.

We were not a party to any material legal proceedings at March 31, 2023, or at the date of this report except for matters listed below. We cannot currently predict the outcome of these actions.

Natera, Inc.

On January 27, 2020, Natera filed a lawsuit against ArcherDX (a subsidiary of Invitae effective October 2, 2020) in the United States District Court for the District of Delaware, alleging that ArcherDX's products using Anchored Multiplex PCR ("AMP") chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814. On March 25, 2020, ArcherDX filed an answer denying Natera's allegations and asserting certain affirmative defenses and counterclaims, including that U.S. Patent No. 10,538,814 is invalid and not infringed. On April 15, 2020, Natera filed an answer denying ArcherDX's counterclaims and filed an amended complaint alleging that ArcherDX's products using AMP chemistry, including STRATAFIDE, PCM,

LiquidPlex, ArcherMET, FusionPlex, and VariantPlex, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, U.S. Patent No. 10,590,482, and U.S. Patent No. 10,597,708, each of which are held by Natera. Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of such patents. On May 13, 2020, ArcherDX filed an answer to Natera's amended complaint denying Natera's allegations and asserting certain affirmative defenses and counterclaims, including that the asserted patents are invalid and not infringed. On June 3, 2020, Natera filed an answer denying ArcherDX's counterclaims. On June 4, 2020, ArcherDX filed a motion seeking dismissal of Natera's infringement claims against STRATAFIDE, PCM, and ArcherMET, and for a judgment that U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On August 6, 2020, Natera filed another complaint against ArcherDX in the United States District Court for the District of Delaware alleging that ArcherDX's products using AMP chemistry, including STRATAFIDE, PCM, LiquidPlex, ArcherMET, and VariantPlex, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,731,220. Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of the patent. On October 13, 2020, the court issued an order denying ArcherDX's motion for dismissal of Natera's infringement claims against STRATAFIDE, PCM, and ArcherMET, and declined to enter judgment that U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On January 12, 2021, the court issued an order granting Natera leave to amend its complaint to add Invitae as a co-defendant and plead allegations that ArcherDX and Invitae induce end-users to infringe the patents-in-suit. Natera filed its second amended complaint ("Second Amended Complaint") on the same day, with service completed on January 15, 2021. ArcherDX and Invitae filed answers to the Second Amended Complaint on January 26, 2021 and February 5, 2021, respectively, denying Natera's allegations and restating certain affirmative defenses and counterclaims of non-infringement and invalidity. The litigations have now been consolidated for all purposes. A claim construction order was issued on June 28, 2021. On October 27, 2021, Natera filed its third amended complaint ("Third Amended Complaint") to add a Certificate of Correction to U.S. Patent No. 10,590,482. On November 3, 2021, ArcherDX filed its answer and counterclaims to Natera's Third Amended Complaint, adding an inequitable conduct defense and declaratory judgment counterclaims. Discovery concluded in December 2021. On January 21, 2022, Natera, ArcherDX and Invitae moved for summary judgment, wherein Natera seeks a determination on certain legal and equitable defenses and ArcherDX and Invitae seek a determination of non-infringement and invalidity of the asserted patents. Those motions were denied by order dated February 6, 2023, and trial began on May 8, 2023.

In addition, on October 6, 2020, Natera filed a complaint against Genosity in the United States District Court for the District of Delaware, alleging that Genosity's use of its AsTra products, and the manufacture, use, sale, and offer for sale of such products, infringes U.S. Patent No. 10,731,220. Natera's complaint further alleges that Genosity's accused products use ArcherDX's ctDNA and region-specific primers. Genosity filed an answer to the complaint on February 15, 2021, denying Natera's allegations and setting forth affirmative defenses and counterclaims of non-infringement, invalidity and unenforceability due to inequitable conduct. On March 8, 2021, Natera filed a motion to dismiss and strike certain affirmative defenses and counterclaims brought by Genosity relating to inequitable conduct. The court denied that motion on March 14, 2022. The court granted an order granting the parties' stipulated request to stay the case on April 1, 2022.

QIAGEN Sciences

On July 10, 2018, ArcherDX and the General Hospital Corporation d/b/a Massachusetts General Hospital, which we refer to as MGH, filed a lawsuit in the United States District Court for the District of Delaware against QIAGEN Sciences, LLC, QIAGEN LLC, QIAGEN Beverly, Inc., QIAGEN Gaithersburg, Inc., QIAGEN GmbH and QIAGEN N.V., which is collectively referred to herein as QIAGEN, and a named QIAGEN executive who was a former member of ArcherDX's board of directors, alleging several causes of action, including infringement of the '810 Patent, trade secret misappropriation, breach of fiduciary duty, false advertising, tortious interference and deceptive trade practices. The '810 Patent relates to methods for preparing a nucleic acid for sequencing and aspects of ArcherDX's AMP technology. On October 30, 2019, with the permission of the Court, ArcherDX amended ArcherDX's complaint to add a claim for infringement of the '597 Patent. The '597 Patent relates to methods of preparing and analyzing nucleic acids, such as by enriching target sequences prior to sequencing, and aspects of ArcherDX's AMP technology. The QIAGEN products that ArcherDX alleges infringe the '810 Patent and the '597 Patent include, but are not limited to, QIAseq Targeted DNA Panels, QIAseq Targeted RNAscan Panels, QIAseq Index Kits and QIAseq Immune Repertoire RNA Library Kits. ArcherDX is seeking, among other things, damages for ArcherDX's lost profits due to QIAGEN's infringement and a permanent injunction enjoining QIAGEN from marketing and selling the infringing products and from using ArcherDX's trade secrets. On December 5, 2019, QIAGEN and the named QIAGEN executive submitted their answer denying the allegations in ArcherDX's complaint and asserting affirmative defenses that, among other things, the '810 Patent and '597 Patent are not infringed by

QIAGEN's products, that both patents are invalid, and that the complaint fails to state any claim for which relief may be granted. On March 1, 2021, each of ArcherDX and QIAGEN moved for summary judgment on issues relating to infringement and validity of ArcherDX's patents, breach of fiduciary duty and trade secret misappropriation. On June 18, 2021, ArcherDX informed the court that it would not assert the following claims to streamline the issues for trial: trade secret misappropriation, false advertising, deceptive trade practices, and tortious interference. The court denied QIAGEN's motion for summary judgment on trade secret misappropriation as moot on June 21, 2021, denied QIAGEN's motion for summary judgment on breach of fiduciary duty on July 26, 2021, and granted QIAGEN's motion for summary judgment of no literal infringement of the '810 Patent on August 21, 2021. Trial proceeded on August 23 through August 27, 2021, resulting in a unanimous jury verdict, which found that: (i) all asserted claims of the '810 and '597 Patents are valid, (ii) QIAGEN willfully infringed the asserted claims of the '810 patent (under the doctrine of equivalents) and the '597 patent (literal infringement), and (iii) ArcherDX and MGH are entitled to recover approximately \$4.7 million in damages. On September 30, 2022, the court issued an order denying QIAGEN's post-trial motion for a new trial or altered verdict, granting ArcherDX's post-trial motion for ongoing royalty at a rate of 7% along with supplemental damages and interest, and denying ArcherDX's motion for an injunction with leave to renew after an evidentiary hearing. No date has been set for the hearing on ArcherDX's request for an injunction.

8. Stockholders' equity

Shares outstanding

Shares of common stock were as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Common stock:		
Shares outstanding, beginning of period	245,562	228,116
Common stock issued in connection with the convertible senior notes exchange	14,220	—
Common stock issued on exercise of stock options, net	1	87
Common stock issued pursuant to vesting of RSUs	715	621
Common stock issued pursuant to acquisitions	177	—
Shares outstanding, end of period	<u>260,675</u>	<u>228,824</u>

Common Stock

As of March 31, 2023 and December 31 2022, we had 600 million shares of common stock authorized with a par value of \$0.0001.

Convertible preferred stock

In August 2017, in a private placement to certain accredited investors, we issued shares of our Series A convertible preferred stock which are convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like. The Series A convertible preferred stock is a non-voting common stock equivalent with a par value of \$0.0001 and has the right to receive dividends first or simultaneously with payment of dividends on common stock. In the event of any liquidation or dissolution of the Company, the Series A preferred stock is entitled to receive \$0.001 per share prior to the payment of any amount to any holders of capital stock ranking junior to the Series A preferred stock and thereafter shall participate pari passu with the holders of our common stock (on an as-if-converted-to-common-stock basis). As of March 31, 2023 and December 31, 2022, we had 20 million shares of preferred stock authorized, of which 3,458,823 shares were designated as Series A convertible preferred stock. As of March 31, 2023 and December 31, 2022, there were no shares of preferred stock or Series A convertible preferred stock outstanding.

Sales Agreement

In May 2021, we entered into a sales agreement (the "2021 Sales Agreement") with Cowen and Company, LLC ("Cowen") under which we may offer and sell from time to time at our sole discretion shares of our common stock through Cowen as our sales agent, in an aggregate amount not to exceed \$400.0 million. Per the terms of the agreement, Cowen will receive a commission of up to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2021 Sales Agreement.

During the three months ended March 31, 2023 and 2022, we did not sell any common stock under the 2021 Sales Agreement.

Senior Secured 2028 Notes

In connection with the issuance of the Senior Secured 2028 Notes on March 7, 2023, we and Deerfield Partners, L.P. (the "selling stockholder"), also entered into a registration rights agreement ("Registration Rights Agreement"). Pursuant to the Registration Rights Agreement, on March 17, 2023, we filed a registration statement to register 111,627,888 shares of common stock issuable upon conversion of the Series B Notes or exercise of the warrants ("Registrable Securities") issuable in connection with certain prepayments of the Series B Notes or Series A Notes, which registration statement was declared effective on April 21, 2023. The selling stockholder may from time to time offer and sell any or all of such issued shares of common stock. We will not receive any proceeds from the sale of shares of our common stock by the selling stockholder. We will receive the proceeds from any exercise of the warrants on a cash basis.

Additionally, under the terms of the purchase and exchange agreements, we exchanged \$305.7 million aggregate principal amount of 2024 Notes for \$275.3 million aggregate principal amount of Series A Notes and 14,219,859 shares of the Company's common stock, and we issued and sold \$30.0 million aggregate principal amount of Series B Notes for cash. See Note 7, "Commitments and contingencies" under the heading "Convertible senior notes—Convertible senior secured notes due 2028" for additional information.

9. Stock incentive plans

Stock incentive plans

In 2010, we adopted the 2010 Incentive Plan (the "2010 Plan"). The 2010 Plan provides for the granting of stock-based awards to employees, directors and consultants under terms and provisions established by our board of directors. Under the terms of the 2010 Plan, options may be granted at an exercise price not less than the fair market value of our common stock. For employees holding more than 10% of the voting rights of all classes of stock, the exercise prices for incentive and nonstatutory stock options must be at least 110% of fair market value of our common stock on the grant date, as determined by our board of directors. The terms of options granted under the 2010 Plan may not exceed ten years.

In January 2015, we adopted the 2015 Stock Incentive Plan (the "2015 Plan"), which became effective upon the closing of our initial public offering. Shares outstanding under the 2010 Plan were transferred to the 2015 Plan upon effectiveness of the 2015 Plan. The 2015 Plan provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 through January 1, 2025. In addition, shares subject to awards under the 2010 Plan that are forfeited or terminated will be added to the 2015 Plan. The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock units, stock appreciation rights and other forms of equity compensation, all of which may be granted to employees, including officers, non-employee directors and consultants. Additionally, the 2015 Plan provides for the grant of cash-based awards.

Options granted generally vest over a period of four years. Typically, the vesting schedule for options granted to newly hired employees provides that 1/4 of the award vests upon the first anniversary of the employee's date of hire, with the remainder of the award vesting monthly thereafter at a rate of 1/48 of the total shares subject to the option. All other options typically vest in equal monthly installments over the four-year vesting schedule. Upon the acquisition of ArcherDX in October 2020, any option that was outstanding was converted into a fully vested option to purchase a share of our common stock, which resulted in the issuance of options to purchase 3.7 million shares of our common stock.

Restricted stock units ("RSUs") generally vest ratably in annual installments over a period of three years, commencing on the first anniversary of the grant date, with certain awards that include a portion that vests immediately upon grant. The vesting schedule for the 2022 grants approved in April 2022 provides that the awards vest ratably in quarterly installments over a period of two years, with certain awards that include a portion that vests immediately upon grant. Grants to the executive team in 2022 vest ratably in annual installments over a period of three years. We have also granted certain awards in connection with our management incentive plan that vest over a period of two years.

In April 2021, we granted RSUs in connection with the acquisition of Genosity Inc. ("Genosity") having a value of up to \$5.0 million to certain continuing employees. During both the three months ended March 31, 2023 and 2022, we recognized \$0.4 million in stock-based compensation expense primarily reported in research and development expense in our condensed consolidated statements of operations. In September 2021, we granted RSUs in connection with the acquisition of the Ciitizen Corporation having a value of up to \$246.9 million to certain

continuing employees. During the three months ended March 31, 2023 and 2022, we recognized stock-based compensation expense of \$14.7 million and \$24.9 million, respectively, primarily reported in research and development expense in our condensed consolidated statements of operations.

Activity under the 2010 Plan and the 2015 Plan is set forth below (in thousands, except per share data and years):

	Shares Available For Grant	Stock Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balances at December 31, 2022	12,625	2,541	\$ 8.49	6.6	\$ 16
Additional shares reserved	9,822	—			
Options granted	(29)	29	2.46		
Options cancelled	257	(257)	8.20		
Options exercised	—	(1)	0.86		
RSUs and PRSUs granted	(197)	—			
RSUs and PRSUs cancelled	425	—			
Balances at March 31, 2023	<u>22,903</u>	<u>2,312</u>	\$ 8.45	6.7	\$ 4
Options exercisable at March 31, 2023		<u>1,163</u>	\$ 11.94	4.2	\$ 4
Options vested and expected to vest at March 31, 2023		<u>2,118</u>	\$ 8.94	6.4	\$ 4

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of our common stock for stock options that were in-the-money.

The following table summarizes RSU, including PRSU, activity (in thousands, except per share data):

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance at December 31, 2022	11,895	\$ 11.70
RSUs granted	197	\$ 2.27
RSUs vested	(715)	\$ 10.47
RSUs cancelled	(425)	\$ 13.54
Balance at March 31, 2023	<u>10,952</u>	\$ 11.54

Stock-based compensation

The following table summarizes stock-based compensation expense included in the condensed consolidated statements of operations (in thousands):

	Three Months Ended March 31,	
	2023	2022
Cost of revenue	\$ 948	\$ 1,865
Research and development	18,846	31,994
Selling and marketing	2,599	2,909
General and administrative	6,589	10,054
Restructuring and other costs	211	—
Total stock-based compensation expense	<u>\$ 29,193</u>	<u>\$ 46,822</u>

Stock-based compensation expense included in restructuring expense was related to the accelerated vesting of RSUs held by certain employees whose employment was terminated as part of the strategic realignment.

10. Restructuring and other costs

In July 2022, we initiated a strategic realignment of our operations to reduce operating costs and drive future growth aligned with our core genetic testing and data platform and patient network. The strategic realignment includes a reduction in workforce, lab and office space consolidation, portfolio optimization, decrease in other operating expenses, as well as a reduced international footprint. Under this strategic realignment, we reduced our workforce by approximately 1,000 employees with a majority of these employees separating from the Company by September 30, 2022 and the remaining affected employees transitioning over varying periods of time up to 12

months. Employees who were impacted by the restructuring were eligible to receive severance benefits contingent upon an impacted employee's execution (and non-revocation, where applicable) of a separation agreement, which included a general release of claims against us.

The following table summarizes the expenses related to our strategic realignment recognized in restructuring and other costs in our condensed consolidated statement of operations (in thousands):

	Three Months Ended March 31, 2023
Employee severance and benefits	\$ 1,283
Impairments and losses on disposals of long-lived assets, net	50,354
Other restructuring costs	919
Total restructuring and other costs	<u>\$ 52,556</u>

Employee severance and benefits are comprised of severance, other termination benefit costs, and stock-based compensation expense for the acceleration of RSUs related to workforce reductions. See Note 9, "Stock incentive plans" for additional information about the accelerated vesting of RSUs. Asset impairments and losses on asset disposals, net include operating lease impairments, losses on disposals of leasehold improvements associated with the exit of certain lab and office space and the related equipment. See Note 7, "Commitments and contingencies" under the heading "Leases" for additional information about operating lease impairments. See Note 5, "Balance sheet components" for additional information about net losses on disposal of property and equipment. Other restructuring costs include professional fees in relation to restructuring activities and contract exit costs including our decision to cease development of acquired technology. See Note 4, "Intangible assets" for additional information. There were no restructuring and other costs for the three months ended March 31, 2022.

We expect to incur additional employee severance and benefits expenses up to \$0.6 million, and additional other restructuring costs primarily related to third-party costs up to \$5.5 million. This reflects the best estimate of the Company as of the date hereof, which may be revised in subsequent periods as the strategic realignment plan progresses.

The following table summarizes the changes in liabilities associated with our strategic realignment initiatives, including restructuring and other costs incurred and cash payments as of March 31, 2023 (in thousands):

	Employee severance and benefits	Other restructuring costs	Total
Beginning balance	\$ —	\$ —	\$ —
Accruals	35,237	7,405	42,642
Payments	(32,974)	(5,464)	(38,438)
Balance at December 31, 2022	<u>2,263</u>	<u>1,941</u>	<u>4,204</u>
Accruals	1,072	994	2,066
Payments	(2,486)	(1,223)	(3,709)
Balance at March 31, 2023	<u>\$ 849</u>	<u>\$ 1,712</u>	<u>\$ 2,561</u>

The restructuring liabilities are included in accrued liabilities in the condensed consolidated balance sheets. We expect that substantially all of the remaining accrued restructuring liabilities will be paid in cash in 2023. The charges recognized in the roll forward of our accrued restructuring liabilities do not include items charged directly to expense for asset impairments and losses on disposals of long-lived assets, accelerated vesting of RSUs, and other periodic exit costs, as those items are not reflected in our restructuring liabilities in our condensed consolidated balance sheets.

11. Income taxes

During the three months ended March 31, 2023 and 2022, we recorded an income tax benefit of \$1.0 million and \$34.9 million, respectively. The income tax benefit for the three months ended March 31, 2023 is primarily related to a \$0.9 million release of federal valuation allowances as a result of impact on our deferred taxes related to Internal Revenue Code Section 174 research and experimental expense capitalization and right-of-use and fixed assets impairment, which enabled the associated deferred tax liability to serve as a source of income to support the realization of existing deferred tax assets for which a valuation allowance had previously been established.

As of March 31, 2023, we maintained \$59.3 million of unrecognized tax benefits, of which \$0.2 million, if recognized, would affect the Company's effective tax rate. The remainder has been recorded as a reduction to the Company's deferred tax assets and, if recognized, would not have an impact on the effective tax rate due to existing valuation allowance against such deferred tax assets. It is possible that the Company's unrecognized tax benefits could change within the next twelve months due to activities of tax authorities, including possible settlement of audits, should any arise, or through normal expiration of statutes of limitations.

The Company's policy is to include penalties and interest expense related to income taxes as a component of tax expense. As of March 31, 2023, there were no accrued interest and penalties related to the unrecognized tax benefits.

Effective for tax years beginning on or after January 1, 2022, pursuant to the Tax Cuts and Jobs Act of 2017, companies are required to capitalize and amortize Internal Revenue Code Section 174 research and experimental expenses paid or incurred over five years for research and development performed in the United States and 15 years for research and development performed outside of the United States. As a result of the Internal Revenue Code Section 174 research and experimental expense capitalization, the Company recognized a deferred tax asset for the future tax benefit of the amortization deductions with offsetting increase in the valuation allowance on deferred tax assets.

The Inflation Reduction Act of 2022 ("IRA") was signed into law on August 16, 2022. The bill was meant to address the high inflation rate in the U.S. through various climate, energy, healthcare and other incentives. These incentives are meant to be paid for by the tax provisions included in the IRA, such as a new 15 percent corporate minimum tax, a 1 percent new excise tax on stock buybacks, additional IRS funding to improve taxpayer compliance and others. At this time, none of the IRA tax provisions are expected to have a material impact to the Company's tax provision. The Company will continue to monitor for updates to the Company's business along with guidance issued with respect to the IRA to determine whether any adjustments are needed to the Company's tax provision in future periods.

12. Net loss per share

The following table presents the calculation of basic and diluted net loss per share (in thousands, except per share data):

	Three Months Ended March 31,	
	2023	2022
Net loss	\$ (192,183)	\$ (181,859)
Shares used in computing net loss per share, basic and diluted	249,907	228,470
Net loss per share, basic and diluted	\$ (0.77)	\$ (0.80)

Common stock issuable in connection with our Convertible Senior Notes and the Senior Secured 2028 Notes participate in any dividends that may be declared by the Company and are therefore considered to be participating securities. The net losses were attributable entirely to common stockholders since the participating securities did not have a contractual obligation to share in the Company's losses.

The following common stock equivalents have been excluded from diluted net loss per share because their inclusion would be anti-dilutive (in thousands):

	Three Months Ended March 31,	
	2023	2022
Shares of common stock subject to outstanding options	2,366	2,972
Shares of common stock subject to outstanding RSUs and PRSUs	11,399	15,935
Shares of common stock pursuant to ESPP	3,528	1,428
Shares of common stock subject to convertible senior notes conversion	28,122	38,403
Shares of common stock subject to convertible senior secured notes conversion	32,866	—
Total shares of common stock equivalents	78,281	58,738

13. Geographic information

Revenue by country is determined based on the billing address of the customer and is summarized as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
United States	\$ 110,464	\$ 108,295
Canada	2,101	2,297
United Kingdom	1,186	2,147
Rest of world	3,605	10,952
Total revenue	<u>\$ 117,356</u>	<u>\$ 123,691</u>

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the related notes and other financial information included in Part I, Item 1. of this Form 10-Q, and together with our audited consolidated financial statements and the related notes and other information included in our Annual Report on Form 10-K for the year ended December 31, 2022. Historic results are not necessarily indicative of future results.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this report other than statements of historical fact, including statements identified by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions, are forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our views regarding the future of genetic testing and its role in mainstream medical practice;
- the impact of the COVID-19 pandemic on our business and the actions we have taken or may take in response thereto;
- our mission and strategy for our business, products and technology;
- the implementation of our business model and the success of our strategic realignment efforts;
- the expected costs and benefits of our strategic realignment, including anticipated annualized cash savings, and our ability to achieve positive operating cash flow;
- the expected benefits from and our ability to integrate our acquisitions;
- our ability to obtain regulatory approvals for our tests;
- the rate and degree of market acceptance of our tests and genetic testing generally;
- our ability to scale our infrastructure and operations in a cost-effective manner;
- our expectations regarding our platform and future offerings;
- the timing and results of studies with respect to our tests;
- developments and projections relating to our competitors and our industry;
- our competitive strengths;
- the degree to which individuals will share genetic information generally, as well as share any related potential economic opportunities with us;
- our commercial plans;
- our ability to obtain and maintain adequate reimbursement for our tests;
- regulatory, political and other developments in the United States and foreign countries;
- our ability to attract and retain key scientific, sales, engineering or management personnel;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- the effects of litigation or investigations on our business;
- our ability to obtain funding for our operations and to service and repay our debt;
- our future financial performance;
- our beliefs regarding our future growth and the drivers of such growth;
- our expectations regarding environmental, social and governance matters;
- the impact of accounting pronouncements and our critical accounting policies, judgments, estimates and assumptions on our financial results;
- our expectations regarding our future revenue, cost of revenue, operating expenses and capital expenditures, and our future capital requirements;
- the impact of macroeconomic conditions, including inflation and recession, on our business; and
- the impact of tax laws on our business.

Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. Although we believe that the expectations and assumptions reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Any forward-looking statements in this report speak

only as of the date of this report. We expressly disclaim any obligation or undertaking to update any forward-looking statements.

In this report, all references to "Invitae," "we," "us," "our," or "the Company" mean Invitae Corporation.

Invitae and the Invitae logo are trademarks of Invitae Corporation. We also refer to trademarks of other companies and organizations in this report.

Summary of risk factors

Our business is subject to numerous risks and uncertainties that could affect our ability to successfully implement our business strategy and affect our financial results. You should carefully consider all of the information in this Quarterly Report and, in particular, the following principal risks and all of the other specific factors described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q before deciding whether to invest in our company.

- We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.
- Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.
- Our strategic realignment and the associated headcount reduction have and are expected to significantly change our business, result in significant expense, may not result in anticipated savings, and will disrupt our business.
- We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.
- If third-party payers, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.
- We need to scale our infrastructure in advance of demand for our tests and other services, and our failure to generate sufficient demand for our tests and other services would have a negative impact on our business and our ability to attain profitability.
- The global macroeconomic environment could negatively impact our business, our financial position and our results of operations.
- We face risks related to health epidemics, including the ongoing COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.
- We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the markets in which we operate. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.
- The market for patient data software is competitive, and our business will be adversely affected if we are unable to successfully compete.
- Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- If we are not able to continue to generate substantial demand for our tests, our commercial success will be negatively affected.
- Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.
- Impairment in the value of our intangible assets has and may in the future have a material adverse effect on our operating results and financial condition.
- We have a large amount of debt, servicing our debt requires a significant amount of cash, we may not have sufficient cash flow from our business to service our debt, and we may need to refinance all or a significant portion of our debt.

- If the FDA regulates the tests we currently offer as LDTs as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.
- One of our competitors has alleged that our Anchored Multiplex PCR, or AMP, chemistry and products using AMP are infringing on its intellectual property, and we may be required to redesign the technology, obtain a license, cease using the AMP chemistry altogether and/or pay significant damages, among other consequences, any of which would have a material adverse effect on our business as well as our financial condition and results of operations.

Mission and strategy

Invitae's mission is to bring comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people.

We were founded on four core principles:

- Patients should own and control their own genetic information;
- Healthcare professionals are fundamental in ordering and interpreting genetic information;
- Driving down the price of genetic information will increase its clinical and personal utility; and
- Genetic information is more valuable when shared.

Our strategy for long-term, profitable growth centers on seven key drivers of our business, which we believe work in conjunction to create a flywheel effect extending our leadership position in the new market we are building:



Those key drivers include:

- **Customer experience:** We see customer experience for patients, providers, and partners as integral to our long-term growth strategy and as an under-utilized catalyst to move genetics into mainstream medicine. Our view is that providing great service and enabling "ease-of-use", such as efficient ordering, comprehensive choices, and reliable turnaround time, are especially important for physicians.
- **Adoption:** As we improve customer experience, we expect more physicians would be open and more willing to increase genetic information in their practice. This is particularly true in fostering adoption among non-genetic experts, who are often the first contact for patients in a health journey. This work will be in parallel with our efforts in producing research supporting guideline expansion and broader advocacy for the benefits of genetic testing.

- **Attract partners.** As we continue to gain adoption and expand our reach, our value proposition to potential partners should increase. These include patient advocacy groups, biopharma partners that utilize our data, testing, network, and services, as well as health systems that intend to implement comprehensive precision medicine.
- **Insights and solutions:** In parallel with bringing new tools and products to the market, our capability to combine phenotypic and genotypic data, through both our genetic testing and third-party patient data, we believe produces a rich dataset that is highly attractive to biopharma partners, patient advocacy groups and more. We believe our services allow our strategic partners to be more precise and move faster with their efforts, such as identifying and recruiting patients, enabling Investigational New Drug (IND) filings, structuring clinical trials, and eventually bringing new therapies to market.
- **Lower cost and higher reimbursement:** As our network continues to scale, we expect to lower our costs and increase our margin, while continuing our pursuit of affordable prices to drive accessibility of genetic information. Our ability to sustainably provide affordable pricing is also expected to be balanced by our success in improving reimbursements and cash collection. Through the generation of scientific evidence and proactive engagement with stakeholders, we intend to pursue better payment and additional coverage.
- **Affordability and accessibility:** As we progress, we anticipate having more flexibility in our pricing strategy, aiming at more affordability and accessibility of our products for more patients.
- **More patients served:** All of these efforts should compound upon each other, expanding our reach and increasing the value of each offering, ultimately serving more patients.

Ultimately, we anticipate more solutions to further improve customer experiences, which in turn feed more answers for patients, foster greater adoption, and bring on more partners to create a flywheel effect.

Business overview

We are focused on making comprehensive, high-quality medical genetic testing information more accessible and instrumental to the healthcare ecosystem and stakeholders, including patients, healthcare providers, payers, biopharma partners, patient advocacy groups and more. We offer genetic testing across multiple clinical areas, including hereditary cancer, precision oncology, women's health, rare diseases and pharmacogenomics. Medical genetics is central to health outcomes and we are working to bring it to the mainstream by enhancing the customer experience, lowering costs, removing barriers to adoption, and expanding insights and solutions. Ultimately, we expect the utility of the accumulated data will compound, enabling improved individual and population health and advancing the benefits of molecular medicine around the globe.

For the years ended December 31, 2022, 2021 and 2020, our revenue was \$516.3 million, \$460.4 million, and \$279.6 million, respectively, and we incurred net losses of \$3.1 billion, \$379.0 million, and \$602.2 million, respectively. For the three months ended March 31, 2023 and 2022, our revenue was \$117.4 million and \$123.7 million, respectively, and we recognized net losses of \$192.2 million and \$181.9 million, respectively. At March 31, 2023, our accumulated deficit was \$5.0 billion.

In 2022, 2021 and 2020, we generated 1,290,000, 1,169,000 and 659,000 billable units, respectively. In the three months ended March 31, 2023, we generated 255,000 billable units compared to 322,000 billable units in the same period in 2022. We calculate volume using billable units, which are billable events that include individual test reports released and individual reactions shipped related to our precision oncology products. We refer to the set of reagents needed to perform a next generation sequencing ("NGS") test for our research use only ("RUO") product as a "reaction." As part of the strategic realignment, we discontinued the sale of and sublicensed to others our distributed precision oncology products, which includes our RUO kit and IVD product offerings. Approximately 36% of the billable volume generated in the first three months of 2023 were billable to patients and institutional customers (e.g., hospitals, clinics, medical centers, biopharmaceutical partners), and the remainder were billable to government and private insurance payers. Many of the gene tests on our assays are reimbursable by health insurance companies. However, when we do not have reimbursement policies or contracts with private insurers, or at times due to other situations, our claims for reimbursement may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. Even if we are successful in achieving reimbursement, we may be paid at lower rates than if we were under contract with the third-party payer. When there is not a contracted rate for reimbursement, there is typically a greater payment requirement from the patient that may result in further delay in payment for these tests.

We believe that the keys to long-term profitable growth are:

- **Consistently improve the client experience:** efficient ordering; comprehensive choices; reliable turnaround time; easy-to-use;
- **Lower costs and higher reimbursement:** align our cost structure with our streamlined product portfolio and implement operational discipline; reduce the costs associated with performing our genetic tests; achieve broad reimbursement coverage for our tests from third-party payers and increase the amount we receive from other types of payers; focus our efforts on testing categories that are more regularly reimbursed to avoid the process of appeals and slow or non-existing payment;
- **Advance insights and solutions:** optimize the amount of genetic content we offer and is used by providers across the range of healthcare platforms; deliver actionable insights through digital health solutions; develop our data services;
- **Improve affordability and accessibility and serve more patients:** provide affordable pricing for genetic analysis and interpretation; partner to reach underserved populations; expand call points;
- **Drive adoption:** increase physician and patient utilization of our platform for ordering and delivery of results; and
- **Attract new partners:** increasing the number of strategic partners working with us to add value for all our customer segments.

Strategic realignment

On July 18, 2022, we initiated a strategic realignment of our operations and began implementing cost reduction programs in order to accelerate our path to positive operating cash flow. We are in the process of realigning and sharpening our focus on the portfolio of businesses that we believe can generate margins and deliver returns to fuel future investment. In the testing business, we have shifted operational and commercial efforts to accelerate positive cash flow by maintaining robust support of the higher-margin, higher-growth testing opportunities among hereditary cancer, precision oncology, women's health, rare disease and pharmacogenomics. We also plan to continue our expansion and integration of key digital health-based technologies and services in order to create a differentiated model in genetic health. Longer-term, we remain committed to our data platform and patient network. We believe that we hold significant growth potential and intend to continue to prioritize the tools, partnerships and applications that support the development of this platform as the catalyst for the future of healthcare.

The strategic realignment included a reduction in workforce of approximately 1,000 positions, lab and office space consolidation, portfolio optimization, decrease in other operating expenses, as well as a reduced international footprint. Management currently expects the strategic realignment will be completed in 2023 and estimates that the total costs incurred may be up to \$170 million for associated employee severance and benefits, asset impairments and losses on disposals of long-lived assets, and other restructuring costs related to the realignment. This reflects the best estimate of management as of the date hereof, which may be revised in subsequent periods as the strategic realignment progresses. The estimate of total cost incurred excludes the \$47.4 million gain on the sale of the RUO kit assets recognized during the three months ended December 31, 2022. We anticipate annualized cash savings of approximately \$326 million, which is expected to be fully realized by the end of 2023. We may not realize, in full or in part, the anticipated annualized cash savings due to unforeseen difficulties or delays in implementing further decreases in other operating expenses.

We expect to continue to incur operating losses for the near term as we execute the strategic realignment of our operations. If we are unable to achieve these objectives and successfully grow revenue and manage our costs, we may not be able to achieve positive operating cash flow in the near term or at all.

Russia and Ukraine Conflict

During the first quarter of 2022, Russia commenced a military invasion of Ukraine, and the ensuing conflict has created disruption in the region and around the world. We have suspended operations in Russia, which has not had and is not expected to have a material impact on our operating results. We serve customers globally across a broad geographic base. Neither Russia nor Ukraine has comprised or is expected to comprise a material portion of our total revenue, net loss, or net assets. We continue to closely monitor the ongoing conflict and related sanctions, which could impact our financial results in the future. Other impacts due to this evolving situation are currently unknown and could potentially subject our business to adverse consequences should the situation escalate beyond its current scope. See Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q for additional

information about the conflict between Russia and Ukraine and its potential effect on our business and results of operations.

Adverse macroeconomic conditions

Adverse macroeconomic developments, including inflation, slowing growth, rising interest rates, or recession, may adversely affect our business and financial condition. These developments have caused, and could in the future cause, disruptions and volatility in global financial markets, including in banking and financial institutions, and increased rates of default and bankruptcy, and negatively affect business and consumer spending. Adverse economic conditions may also increase the costs of operating our business, including vendor, supplier and workforce expenses, and may limit our access to capital or may significantly increase our cost of capital. Management continues to evaluate the impact of macroeconomic events, including inflation, on our business and our future plans and intends to take appropriate measures to help alleviate their impact, but there can be no assurance that these efforts will be successful.

Impact of COVID-19

We expect the COVID-19 pandemic may continue to impact our business. We have reviewed and adjusted, when necessary, for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

In response to the pandemic, we have implemented measures to protect the health of all of our employees during this time with additional measures in place to better protect our on-site lab production and support teams. Our production facilities currently remain fully operational. Substantially all of the Company's offices have re-opened in a hybrid working model, subject to operating restrictions which adhere to healthcare guidelines to protect public health and the health and safety of employees. We continue to monitor, update and align our corporate policies to meet state and federal occupational health and safety rules. While we have not experienced significant disruption in our supply chain, we have experienced supply delays as a result of the COVID-19 pandemic and have also had to obtain supplies from new suppliers.

As a result of government-imposed restrictions, many announced healthcare guidelines resulted in a shift of regular physician visits and healthcare delivery activities to remote/telehealth formats. This is particularly important for patients who, despite the fall-out from COVID-19, continued to be diagnosed with critical diseases, like cancer, and for women who are pregnant or are trying to conceive. We believe our investments in new access platforms and technologies position us well to provide a range of testing to clinicians and patients using a "clinical care from afar" model. An example is our Gia telehealth platform, which expands access to remote interaction between patients and clinicians as well as direct ordering of genetic tests.

Although many government-imposed restrictions have been reduced or eliminated, the future impact of the COVID-19 pandemic continues to be highly uncertain. Given the unknown duration and extent of COVID-19's impact on our business, and the healthcare system in general, we continue to monitor evolving market conditions and have pivoted our focus and investments on the commercial execution of workflows that support remote ordering, online support and telehealth.

Factors affecting our performance

Number of billable units

Our test revenue is tied to the number of tests which we bill patients, third-party payers that pay on behalf of patients, and institutions (e.g., hospitals, clinics, medical centers, biopharmaceutical partners). We refer to billable events that include individual test reports released and individual reactions shipped as billable units. We refer to the set of reagents needed to perform an NGS test for our RUO kit product as a "reaction." We typically bill for our services following delivery of the billable report derived from testing samples and interpreting the results. For units manufactured for use by customers in distributed facilities, we typically bill customers upon shipment of those units. Test orders are placed under signed requisitions or contractual agreements, as we often enter into contracts with insurance companies and institutions. We incur the expenses associated with a unit in the period in which the unit is processed regardless of when payment is received with respect to that unit. We believe the number of billable units in any period is an important indicator of the growth in our testing business, and with time, this will translate into the number of customers accessing our platform.

Number and size of research and commercial partnerships

Pharma development service revenue, which we recognize within other revenue in our condensed consolidated statements of operations, is generated primarily from services provided to biopharmaceutical companies and other partners and is related to companion diagnostic development, clinical research, and clinical trial services across the research, development and commercialization phases of collaborations. The result of these relationships may include the development of new targeted companion diagnostics, which underscore and expand the need for genetic testing and in some cases may lead to intellectual property and/or revenue sharing opportunities with third-party partners. As a result of the strategic realignment, we terminated early or changed the scope of certain collaborations as part of our pharma development services, and are in the process of supporting wind-down activities for certain companion diagnostic development agreements to conclude existing contracts.

Success obtaining and maintaining reimbursement

Our ability to increase volume and revenue will depend in part on our success achieving broad reimbursement coverage and laboratory service contracts for our tests from third-party payers and agreements with institutions and partners. Reimbursement may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary and cost-effective, as well as whether we are in contract, where we get paid more consistently and at higher rates. Because each payer makes its own decision as to whether to establish a policy or enter into a contract to reimburse for our testing services and specific tests, seeking these approvals is a time-consuming and costly process. In addition, clinicians and patients may decide not to order our tests if the cost of the test is not covered by insurance. Because we require an ordering physician to requisition a test, our revenue growth also depends on our ability to successfully promote the adoption of our testing services and expand our base of ordering clinicians. We believe that establishing coverage and obtaining contracts from third-party payers is an important factor in gaining adoption by ordering clinicians. Our arrangements for laboratory services with payers cover approximately 332 million lives, comprised of Medicare, all national commercial health plans, and Medicaid in most states, including California (Medi-Cal), our home state.

Ability to lower the costs associated with performing our tests

Reducing the costs associated with performing our genetic tests is both a focus and a strategic objective of ours. Over the long term, we will need to reduce the cost of raw materials by improving the output efficiency of our assays and laboratory processes, modifying our platform-agnostic assays and laboratory processes to use materials and technologies that provide equal or greater quality at lower cost, improve how we manage our materials, port some tests onto a next generation sequencing platform and negotiate favorable terms for our materials purchases. We also intend to continue to design and implement hardware and software tools that are designed to reduce personnel-related costs for both laboratory and clinical operations/medical interpretation by increasing personnel efficiency and thus lowering labor costs per test.

Ability to optimize our genetic content in meeting market needs and create new pathways to test

We intend to continue to reduce the average cost per test, optimize our test menus and content, and offer the tests at affordable prices in order to meet customer and patient needs. In addition, we have and intend to continue to identify new ways to connect our testing services and information to patients. These include direct patient outreach and ordering capacity, the use of automated assistants for physician customers to improve the ease of ordering and processing genetic tests and programs designed to reach underserved patient populations with genetic testing. We also continue to collaborate with strategic partners and identify new market and channel opportunities.

Realignment of our business and timing of expenses

As part of the strategic business realignment of our operations announced in July 2022, we initiated a comprehensive plan focused on supporting business lines and geographies that we believe can generate sustainable margins, provide the best return to fuel future investment and accelerate the company's path to positive cash flow. We believe the plan further helps ensure we remain at the forefront of innovation and advancements in genomics by allocating resources towards our core genetic testing and data and patient network platform that have the potential to improve healthcare outcomes.

We conducted an assessment of our product portfolio as well as the associated research and development and commercial spending. Our plan shifts the focus to programs relevant to the core testing business to drive profitable growth. We also performed an extensive review of internal and external costs and how those expenses align with the business structure. Additional savings are expected to be generated through the ongoing digitization

of workflows, elimination of duplication and streamlined processes across the core platforms and rationalization of technology and external services.

As we refocus our operations on our core genomic testing platform, we also plan to continue to invest in our genetic testing and data business to drive long-term profitable growth. We deploy state-of-the-art technologies in our genetic testing services, and we intend to continue to scale our infrastructure, including our testing capacity and capabilities as well as our information systems. We also expect to incur software development costs as we seek to further digitize and automate our laboratory processes and our genetic interpretation and report sign-out procedures, scale our customer service capabilities to improve our clients' experience, and expand the functionality of our website. We will continue to incur costs related to marketing and branding as we expand our initiatives beyond our current customer base and focus on providing access to customers through our website. In addition, we will incur ongoing expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter as we focus on different aspects of our business.

How we recognize revenue

We generally recognize revenue on an accrual basis, which is when a customer obtains control of the promised goods or services, typically a test report, or upon shipment of our precision oncology products. Accrual amounts recognized are based on estimates of the consideration that we expect to receive, and such estimates are adjusted and subsequently recorded until fully settled. Changes to such estimates may increase or decrease revenue recognized in future periods. Revenue from our tests may not be equal to billed amounts due to a number of factors, including differences in reimbursement rates, the amounts of patient payments, the existence of secondary payers and claim denials. Some test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with insurance companies and institutions that include pricing provisions under which such tests are billed.

Pharma development service revenue is generated primarily from custom assay design services, sample processing activities and consultative inputs, which is separate from revenue generated by any related or unrelated product component. Subsequent to the strategic realignment, pharma development service revenue is generated from personalized cancer monitoring services and sample processing activities. Revenue is recognized as services are provided using the input method based on our assessment of performance completed to date toward completion of a contract.

Financial overview

Revenue

We primarily generate revenue from testing services and sales of distributed precision oncology products. Customers are typically billed upon delivery of test results or shipment of products. We also generate revenue from development agreements, access to data, data analytics and other related services provided for biopharma partners and other parties. Our ability to increase our revenue will depend on our ability to increase our market penetration, obtain contracted reimbursement coverage from third-party payers and increase the amount we receive from other types of payers, improve payer collections, and grow our relationships with biopharma partners.

As a result of the strategic realignment, we exited certain product lines including our distributed precision oncology products and terminated early or changed the scope of certain collaborations as part of our pharma development services. We are in the process of supporting wind-down activities for certain companion diagnostic development agreements to conclude existing contracts.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering our products and services and includes expenses for materials and supplies, personnel-related costs, freight, costs for lab services, genetic interpretation and clinical trial support, equipment and infrastructure expenses and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangibles, and utilities. We expect cost of revenue to generally increase in line with an increase in billable volume. We also expect amortization of acquired intangible assets, which is not dependent on billed volume, to remain consistent with 2022 expenses. We anticipate our cost per unit for existing tests will generally decrease over time due to the efficiencies we expect to gain as volume increases, and from other cost reductions achieved through automation, supply chain and logistics initiatives, process standardization, and other cost reductions. These reductions in cost per unit will likely be offset by new offerings, which often have higher costs per unit during the introductory phases before we are able to gain efficiencies. The cost per unit may fluctuate significantly from quarter to quarter.

Operating expenses

Our operating expenses are classified into three categories related to our operational activities: research and development, selling and marketing, and general and administrative. For each category, the largest component is generally personnel-related costs, which include salaries, employee benefit costs, bonuses, commissions, as applicable, and stock-based compensation expense. Operating expenses also include restructuring and other costs, which is discussed below.

Research and development

Research and development expenses represent costs incurred to develop our technology and future offerings. These costs are principally for process development associated with our efforts to expand the number of genes we can evaluate, our efforts to lower the costs per unit and our development of new products to expand our platform. We have and may continue to partner with other companies to develop new technologies and capabilities we expect to invest capital and incur significant operating costs to support these development efforts. In addition, we incur process development costs to further develop the software we use to operate our laboratories, analyze generated data, process customer orders, validate clinical activities, enable ease of customer ordering, deliver reports and automate our business processes. These costs consist of personnel-related costs, laboratory supplies and equipment expenses, consulting costs, amortization of acquired intangible assets, and allocated overhead including rent, information technology, equipment depreciation and utilities.

We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to decrease in fiscal year 2023 as compared to fiscal year 2022 as we streamline our product portfolio, shift investments, including the exit of certain business lines and commercial geographies, and reduce labor costs through a reduction in workforce. We expect to make investments to reduce costs and streamline our technology to provide patients access to testing aligned to scale with our long-term profitable growth targets.

Selling and marketing

Selling and marketing expenses consist of personnel-related costs, including commissions, client service expenses, advertising and marketing expenses, educational and promotional expenses, market research and analysis, and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangibles, and utilities. We expect our selling and marketing expenses to decrease in fiscal year 2023 as compared to fiscal year 2022 as a result of a reduction in workforce, targeted sales force expansion and lower marketing spending as a result of a more efficient sales and marketing approach to support our core genetic testing platform.

General and administrative

General and administrative expenses include executive, finance and accounting, billing and collections, legal and human resources functions as well as other administrative costs. These expenses include personnel-related costs; audit, accounting and legal expenses; consulting costs; allocated overhead including rent, information technology, equipment depreciation, and utilities; costs incurred in relation to our co-development agreements; and post-combination expenses incurred in relation to companies we acquire. We expect our general and administrative expenses to decrease in fiscal year 2023 as compared to fiscal year 2022 as a result of our strategic realignment including a reduction in workforce, consolidation of underutilized facilities, digitization of workflows, elimination of duplication and streamlined processes, and rationalization of technology and external services spending.

Restructuring and other costs

Restructuring and other costs include employee severance and benefits, asset impairments and losses on disposals of long-lived assets and other costs. Employee severance and benefit costs are comprised of severance, other termination benefit costs, and stock-based compensation expense for the acceleration of RSUs related to workforce reductions. Employee severance and benefit costs include one-time termination benefits that are recognized as a liability at estimated fair value, at the time of communication to employees, unless future service is required, in which case the costs are recognized ratably over the future service period. Ongoing termination benefits are recognized as a liability at estimated fair value when the amount of such benefits is probable and reasonably estimable. Asset impairments and losses on disposals of long-lived assets include operating lease impairments and losses on disposals of property and equipment and leasehold improvements associated with the exit of certain lab and office space. Other restructuring costs include professional fees and contract exit costs.

Other (expense) income, net

Other (expense) income, net primarily consists of loss on extinguishment of debt, net, debt issuance costs, changes in the fair value of convertible senior secured notes and our acquisition-related liabilities, and interest income generated from our cash equivalents and marketable securities.

Interest expense

Interest expense is primarily attributable to interest incurred related to our debt and finance leases. See Note 7, "Commitments and contingencies" in Notes to Condensed Consolidated Financial Statements in Part I, Item 1. of this Quarterly Report on Form 10-Q for additional information.

Income tax benefit

Since we generally establish a full valuation allowance against our deferred tax assets, our income tax benefit primarily consists of changes in our deferred tax realization assessments as a result of taxable temporary differences assumed in connection with our acquisitions and changes in the expected timing of the reversal of taxable temporary differences.

Critical accounting policies and estimates

Management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. We evaluate our estimates on an ongoing basis. Our estimates are based on current facts, our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that our accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

The following discussion is related to estimating the fair value of our new Senior Secured 2028 Notes as of March 31, 2023, and should be read in conjunction with our critical accounting policies and estimates disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. Except as presented below, there have been no material changes from the critical accounting policies and estimates described in our Annual Report on Form 10-K. See Note 2, "Summary of significant accounting policies" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1. of this Quarterly Report on Form 10-Q for information regarding recent accounting pronouncements.

Fair value of Senior Secured 2028 Notes

We elected the fair value option to measure our Senior Secured 2028 Notes due to the complexity of the various conversion and settlement options available to both the holders of such notes and Invitae. We utilize the binomial lattice model, specifically a lattice model to estimate the fair value of the convertible senior secured notes at issuance and subsequent reporting dates. The estimated fair value of the Senior Secured 2028 Notes is determined using Level 3 inputs and assumptions unobservable in the market. This model incorporates the terms and conditions of the Senior Secured 2028 Notes and assumptions related to stock price, expected stock price volatility, risk-free interest rate, market credit spread, and cost of debt. The stock price is based on the publicly traded price of our common stock as of the measurement date. We estimate the volatility of our stock price based on the historical and implied volatilities of our publicly traded common stock. The risk-free interest rate is based on interpolated U.S. Treasury rates, commensurate with a similar term to the Senior Secured 2028 Notes. We will record changes in fair value, inclusive of accrued interest, through the condensed consolidated statements of operations as a fair value adjustment of the convertible senior secured debt each reporting period, with the portion of the change that results from a change in the instrument-specific credit risk recorded separately in the condensed consolidated statements of comprehensive loss, if applicable.

As of March 31, 2023, the estimated fair value of the Senior Secured 2028 Notes was \$282.9 million. The portion of the estimated fair value of Series A Notes for which conversion is subject to stockholder approval and for which we have a cash settlement obligation is classified as a current liability with the remainder classified as a long-

term liability in the condensed consolidated balance sheets. The current liability was determined based on the product of the shares of common stock in excess of the NYSE Cap multiplied by the arithmetic average of the volume weighted average price of our common stock on each of the five consecutive trading dates immediately preceding March 31, 2023. The long-term liability represents the portion of the Senior Secured 2028 Notes for which we have the intent and the ability to settle the obligations by issuing shares.

The determination of fair value requires considerable judgment and is highly sensitive to changes in underlying assumptions. Remeasuring the fair value of our Senior Secured 2028 Notes on a recurring basis through earnings requires the estimation of significant unobservable inputs, which involve inherent uncertainties and application of management judgment. Using different estimates or assumptions would have materially affected our results. For example, as of March 31, 2023:

- A 1,000 basis point, or ten percent, decrease or increase to the estimated stock price assumption would have decreased or increased, respectively, the estimated fair value of our Senior Secured 2028 Notes and increased or decreased, respectively, the associated gains recognized through first quarter 2023 earnings by \$12.2 million and \$10.1 million, respectively.
- A 1,000 basis point, or ten percent, decrease or increase to the cost of debt assumption would have increased or decreased, respectively, the estimated fair value of our Senior Secured 2028 Notes and decreased or increased, respectively, the associated gains recognized through first quarter 2023 earnings by \$10.9 million and \$12.1 million, respectively.
- A 1,000 basis point, or ten percent, decrease or increase to the estimated stock price volatility assumption would have decreased or increased, respectively, the estimated fair value of our Senior Secured 2028 Notes and increased or decreased, respectively, the associated gains recognized through first quarter 2023 earnings by \$7.3 million and \$4.8 million, respectively.

Results of operations

Three Months Ended March 31, 2023 and 2022

The following sets forth our condensed consolidated statements of operations data for each of the periods indicated (in thousands, except percentage changes). Our historical results are not necessarily indicative of our results of operations to be expected for any future period.

	<u>Three Months Ended March 31,</u>		<u>Dollar</u>	<u>%</u>
	<u>2023</u>	<u>2022</u>	<u>Change</u>	<u>Change</u>
Revenue:				
Test revenue	\$ 112,623	\$ 119,497	\$ (6,874)	(6)%
Other revenue	4,733	4,194	539	13%
Total revenue	<u>117,356</u>	<u>123,691</u>	<u>(6,335)</u>	<u>(5)%</u>
Operating expenses:				
Cost of revenue	88,442	97,116	(8,674)	(9)%
Research and development	61,978	128,236	(66,258)	(52)%
Selling and marketing	44,510	60,144	(15,634)	(26)%
General and administrative	45,241	51,428	(6,187)	(12)%
Restructuring and other costs	52,556	—	52,556	100%
Total operating expenses	<u>292,727</u>	<u>336,924</u>	<u>(44,197)</u>	<u>(13)%</u>
Loss from operations	(175,371)	(213,233)	37,862	18%
Other (expense) income, net:				
Loss on extinguishment of debt, net	(10,822)	—	(10,822)	(100)%
Debt issuance costs	(19,859)	—	(19,859)	(100)%
Change in fair value of convertible senior secured notes	18,304	—	18,304	100%
Change in fair value of acquisition-related liabilities	218	10,003	(9,785)	(98)%
Other income, net	5,883	436	5,447	NM
Total other (expense) income, net	<u>(6,276)</u>	<u>10,439</u>	<u>(16,715)</u>	<u>NM</u>
Interest expense	<u>(11,496)</u>	<u>(13,985)</u>	<u>2,489</u>	<u>18%</u>
Net loss before taxes	(193,143)	(216,779)	23,636	11%
Income tax benefit	960	34,920	(33,960)	(97)%
Net loss	<u>\$ (192,183)</u>	<u>\$ (181,859)</u>	<u>\$ (10,324)</u>	<u>(6)%</u>

NM - Not Meaningful

Revenue

The decrease in total revenue of \$6.3 million for the three months ended March 31, 2023 compared to the same period in 2022 was primarily due to decreased billable volume partially offset by higher average revenue per billable unit. Billable volume decreased due to the exit of certain product offerings, including the RUO kit and IVD product offerings, and geographies as a result of the strategic realignment. Billable volume decreased to approximately 255,000 in the three months ended March 31, 2023 compared to 322,000 in the same period of 2022, a decrease of 21 percent. Average revenue per billable unit was \$442 per unit in the three months ended March 31, 2023 compared to \$372 per unit in the comparable prior period primarily due to changes in payer and product mix.

Cost of revenue

The decrease in the cost of revenue of \$8.7 million for the three months ended March 31, 2023 compared to the same period in 2022 was primarily due to a decrease in billable volume, partially offset by a higher cost per billable unit. Cost per unit was \$347 in the three months ended March 31, 2023 compared to \$302 for the same period in 2022. The cost per unit increased primarily due to lower billable volume and an increase in amortization of acquired intangible assets of \$9.0 million due to a full quarter of amortization expense in 2023 as compared to a partial quarter of amortization expense in 2022 due to the completion of certain in-process research and development ("IPR&D") assets. This increase was offset by lower lab materials costs of \$10.8 million primarily due to a decrease in volume related to the exit of certain product offerings and geographies as a result of the strategic realignment, and change in mix of materials, decreases in personnel-related costs of \$4.4 million due to a reduction in workforce related to our strategic realignment, decreases in information technology costs of \$1.1 million due to lower spending on software licenses and cloud computing, and decreases in other costs of \$1.4 million.

Research and development

The decrease in research and development expense of \$66.3 million for the three months ended March 31, 2023 compared to the same period in 2022 was primarily due to lower personnel-related expenses of \$40.7 million due to the reduction in workforce related to our strategic realignment, decreases in lab-related expenses of \$10.9 million as a result of lower costs related to external development projects and lab supplies and services, decreases in information technology costs of \$4.4 million due to lower spending on software licenses and cloud computing, decreases in facilities-related expenses of \$3.7 million due to lower lease expenses and security and building support costs, decreases in professional fees of \$3.7 million due to lower contract labor, and decreases in other expenses of \$2.9 million.

Selling and marketing

The decrease in selling and marketing expense of \$15.6 million for the three months ended March 31, 2023 compared to the same period in 2022 was primarily due to lower personnel-related expenses of \$11.9 million due to the reduction in workforce related to our strategic realignment, decreases in marketing costs of \$0.7 million as a result of lower spending on brand initiatives and advertising, and decreases in other expenses of \$3.0 million.

General and administrative

The decrease in general and administrative expense of \$6.2 million for the three months ended March 31, 2023 compared to the same period in 2022 was primarily due to lower personnel-related costs of \$8.4 million primarily due to the reduction in workforce related to our strategic realignment, and decreases in professional and outside services of \$3.0 million due to lower contract labor. These decreases were partially offset by lower functional overhead expense allocations related to information technology and facilities-related expenses of \$5.2 million.

Restructuring and other costs

During the three months ended March 31, 2023, we incurred restructuring and other costs of \$52.6 million. Restructuring and other costs were comprised of \$50.4 million in impairments and losses on disposals of long-lived assets, net, \$1.3 million in employee severance and benefits, and \$0.9 million in other restructuring expenses. We did not have similar expenses for the three months ended March 31, 2022. See Note 10, "Restructuring and other costs" in Notes to the Condensed Consolidated Financial Statements in Part I, Item 1. of this Quarterly Report on Form 10-Q for further information.

Loss on extinguishment of debt, net

During the three months ended March 31, 2023, we incurred a net loss on extinguishment of debt of \$10.8 million. In connection with the settlement of our 2020 Term Loan in February 2023, we incurred debt extinguishment costs of \$19.3 million, composed of an \$11.2 million write-off of unamortized debt issuance costs and \$8.1 million of prepayment fees. In February 2023, we also entered into purchase and exchange agreements with certain holders of the outstanding 2024 Notes for the new Senior Secured 2028 Notes, shares of common stock, and cash. These exchanges resulted in a gain on extinguishment of debt of \$8.5 million related to the 2024 Notes. See Note 7, "Commitments and contingencies" in Notes to the Condensed Consolidated Financial Statements in Part I, Item 1. of this Quarterly Report on Form 10-Q for further information.

Debt issuance costs

During the three months ended March 31, 2023, we incurred debt issuance costs of \$19.9 million related to the issuance of our Senior Secured 2028 Notes. See Note 7, "Commitments and contingencies" in Notes to the Condensed Consolidated Financial Statements in Part I, Item 1. of this Quarterly Report on Form 10-Q for further information.

Change in fair value of convertible senior secured notes

During the three months ended March 31, 2023, we recorded a gain of \$18.3 million related to the change in fair value of our Senior Secured 2028 Notes. We elected the fair value option to account for our Senior Secured 2028 Notes, which requires the notes to be measured at their issue-date estimated fair value and then subsequently remeasured at estimated fair value as of each reporting date. The gain during the three months ended March 31, 2023 was primarily due to the decrease in our stock price since the issue-date estimated fair value. See Note 6, "Fair value measurement" and Note 7, "Commitments and contingencies" in Notes to the Condensed Consolidated Financial Statements in Part I, Item 1. of this Quarterly Report on Form 10-Q for further information.

Change in fair value of acquisition-related liabilities

The decrease in change in fair value of acquisition-related liabilities of \$9.8 million for the three months ended March 31, 2023 compared to the same period in 2022 was primarily due to a decrease in fair value adjustments related to our stock payable liabilities as a result of the decrease in the price of our common stock and settlement of acquisition-related hold-backs.

Other income, net

The increase in other income, net of \$5.4 million for the three months ended March 31, 2023 compared to the same period in 2022 was primarily due to an increase in interest income earned on our marketable securities investments.

Interest expense

The decrease in interest expense of \$2.5 million for the three months ended March 31, 2023 compared to the same period in 2022 was primarily due to the repayment of the 2020 Term Loan in February 2023.

Income tax benefit

The decrease in income tax benefit of \$34.0 million for the three months ended March 31, 2023 compared to the same period in 2022 was primarily due to a \$34.6 million release of federal and state valuation allowances for the three months ended March 31, 2022 as a result of the reclassification of ArcherDX's STRATAFIDE and PCM in-process research and development intangibles from indefinite-lived intangibles to developed technology, which enabled the associated deferred tax liability to serve as a source of income to existing finite-lived deferred tax assets for which a valuation allowance had previously been established. There was no similar income tax benefit in the current period for the three months ended March 31, 2023.

Liquidity and capital resources

Liquidity and capital expenditures

We have generally incurred net losses since our inception. For the three months ended March 31, 2023 and 2022, we had net losses of \$192.2 million and \$181.9 million, respectively, and we expect to incur additional losses in the future. At March 31, 2023, we had an accumulated deficit of \$5.0 billion. While our revenue has increased over time, we may never achieve revenue sufficient to offset our expenses.

Since inception, our operations have been financed primarily by fees collected from our customers, net proceeds from sales of our capital stock as well as borrowing from debt facilities and the issuance of convertible senior notes.

In the third quarter of 2022, we issued 2.4 million shares of common stock at an average price of \$3.99 per share in an "at the market" offering for aggregate proceeds of \$10.0 million and net proceeds of \$9.7 million.

In September 2019, we issued \$350.0 million of aggregate principal amount of 2024 Notes, which bear cash interest at a rate of 2.0% per year. Also in September 2019, we used the funds received through the issuance of the 2024 Notes to settle our note purchase agreement we entered into in November 2018. In April 2021, we issued \$1,150.0 million of aggregate principal amount of 2028 Notes, which bear cash interest at a rate of 1.5% per year.

In February 2023, we entered into purchase and exchange agreements with certain holders of the outstanding 2024 Notes. Under the terms of the agreements, we (a) exchanged \$305.7 million aggregate principal amount of 2024 Notes for \$275.3 million aggregate principal amount of Series A Notes and 14,219,859 shares of common stock and (b) issued and sold \$30.0 million aggregate principal amount of Series B Notes for cash. The Senior Secured 2028 Notes bear cash interest at a rate of 4.50% per year.

Prior to such time that we obtain stockholder approval for the issuance of shares of common stock in excess of the limitations imposed by the NYSE Cap, holders of the Series A Notes are prohibited from converting their notes or exercising any warrants issued in respect of those notes in excess of such NYSE Cap and we would instead be required to settle any conversion in cash if we are not able to obtain the stockholder approval prior to September 30, 2023. The cash settlement amount upon conversion of a Series A Note by a holder prior to stockholder approval is equal to the product of the shares of common stock in excess of the NYSE Cap multiplied by the arithmetic average of the volume weighted average price of our common stock on each of the five consecutive trading days immediately preceding the conversion date. After obtaining stockholder approval, the full amount of the outstanding balance of the Senior Secured 2028 Notes will be convertible into shares of common stock, with no conversion limitations. We intend to seek to obtain such stockholder approval at our annual meeting scheduled to be held on June 5, 2023. There can be no assurance that we will be successful in obtaining stockholder approval for the proposal to approve the issuance of shares of common stock pursuant to the conversion of the Senior Secured 2028 Notes or the exercise of any warrants issued in respect to the Senior Secured 2028 Notes in excess of the limitations imposed by the NYSE Cap prior to September 30, 2023. If we fail to obtain stockholder approval, we may not have enough available cash or be able to obtain financing at the time we are required to settle any conversion.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt, including paying off the principal when due, and make necessary capital expenditures. Holders of our convertible senior notes have the right to require us to repurchase all or any portion of their notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments, which could adversely affect our liquidity. However, we only have limited ability to make those cash payments under our credit agreement and, even if the credit agreement limitations are no longer in effect, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of notes surrendered or to repay outstanding notes when they mature.

In October 2020, in connection with our acquisition of ArcherDX, we entered into a credit facility to borrow \$135.0 million which closed concurrently with the merger. The terms of this credit facility restrict our ability to incur certain indebtedness, pay dividends, make acquisitions and take other actions. In February 2023, we repaid, prior to

maturity date, the principal balance outstanding of \$135.0 million plus accrued interest of \$2.6 million and prepayment fees of \$8.1 million.

At March 31, 2023 and December 31, 2022, we had \$171.2 million and \$267.5 million, respectively, of cash, cash equivalents, and restricted cash and marketable securities of \$217.5 million and \$289.6 million, respectively. Our primary use of cash is to fund our operations. Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We have incurred substantial losses since inception, and we expect to continue to incur losses in the near future. We believe our existing cash, cash equivalents and marketable securities as of March 31, 2023 and fees collected from the sale of our products and services will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

We expect to raise additional funding to finance operations and service debt obligations prior to achieving profitability or should we make additional acquisitions. We regularly consider fundraising opportunities and expect to determine the timing, nature and size of future financings based upon various factors, including market conditions, debt maturities and our operating plans. We may in the future elect to finance operations by selling equity or debt securities or borrowing money. If we issue equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing additional debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. In addition, the terms of additional debt securities or borrowings could impose significant restrictions on our operations. If additional funding is required, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all. If we are unable to obtain additional funding when needed, we may need to curtail planned activities to reduce costs. Doing so will likely have an unfavorable effect on our ability to execute on our business plan and have an adverse effect on our business, results of operations and future prospects.

The following table summarizes our cash flows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Net cash used in operating activities	\$ (34,398)	\$ (147,543)
Net cash provided by (used in) investing activities	73,878	(449,456)
Net cash used in financing activities	(135,768)	(920)
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (96,288)</u>	<u>\$ (597,919)</u>

Cash flows from operating activities

For the three months ended March 31, 2023, cash used in operating activities of \$34.4 million principally resulted from our net loss of \$192.2 million, an \$18.3 million gain related to the change in fair value of convertible senior secured notes, \$2.9 million of amortization of premiums and discounts on investment securities, a \$1.0 million income tax benefit, and non-cash charges for remeasurements of liabilities in connection with business combinations of \$0.2 million. These were partially offset by non-cash charges of \$50.4 million related to impairments and losses on disposals of long-lived assets, \$35.0 million for depreciation and amortization, \$29.2 million for stock-based compensation, \$19.9 million of debt issuance costs, \$10.8 million of loss on extinguishment of debt, \$3.1 million of non-cash lease expense, \$3.0 million for amortization of debt discount and issuance costs related to our outstanding debt, \$0.8 million of post-combination share-based compensation expense, and other activities of \$0.8 million. The net effect on cash for changes in net operating assets was an increase of cash of \$27.2 million.

For the three months ended March 31, 2022, cash used in operating activities of \$147.5 million principally resulted from our net loss of \$181.9 million, a \$34.9 million income tax benefit and non-cash charges for remeasurements of liabilities in connection with business combinations of \$9.8 million. These were partially offset by non-cash charges of \$46.8 million for stock-based compensation, \$27.1 million for depreciation and amortization, \$3.9 million for amortization of debt discount and issuance costs related to our outstanding debt and \$1.7 million of post-combination expense. The net effect on cash for changes in net operating assets was a decrease in cash of \$2.8 million.

Cash flows from investing activities

For the three months ended March 31, 2023, cash provided by investing activities of \$73.9 million was primarily due to net purchases and maturities of marketable securities of \$75.2 million and cash used for purchases of property and equipment of \$1.3 million.

For the three months ended March 31, 2022, cash used in investing activities of \$449.5 million was primarily due to net purchases and maturities of marketable securities of \$428.6 million, and cash used for purchases of property and equipment of \$20.8 million.

Cash flows from financing activities

For the three months ended March 31, 2023, cash used in financing activities of \$135.8 million primarily consisted of the repayment of the 2020 Term Loan of \$135.0 million, debt issuance costs related to the convertible senior notes exchange and prepayment fees on our 2020 Term Loan of \$28.0 million, settlement of acquisition obligations of \$1.5 million, and finance lease principal payments of \$1.3 million. These were partially offset by proceeds from the issuance of Series B Notes of \$30.0 million.

For the three months ended March 31, 2022, cash used in financing activities of \$0.9 million primarily consisted of finance lease principal payments of \$1.3 million as well as cash received from issuances of common stock of \$0.4 million.

Contractual obligations

The following table summarizes our contractual obligations, including interest, as of March 31, 2023 (in thousands):

Contractual obligations:	Remainder of 2023	2024 and 2025	2026 and 2027	2028 and beyond	Total
Operating leases	\$ 17,928	\$ 54,807	\$ 39,759	\$ 98,429	\$ 210,923
Finance leases	4,154	3,839	—	—	7,993
Convertible senior notes	—	44,269	—	1,150,000	1,194,269
Convertible senior secured notes	—	—	—	305,257	305,257
Purchase commitments	17,388	17,425	750	—	35,563
Total	\$ 39,470	\$ 120,340	\$ 40,509	\$ 1,553,686	\$ 1,754,005

Operating lease maturity amounts included in the table above do not include sublease income expected to be received under our subleases. We expect to receive sublease income for fiscal years ending December 31, 2023, 2024 and 2025 of \$0.7 million, \$0.9 million and \$0.1 million, respectively.

See Note 7, "Commitments and contingencies" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1. of this Quarterly Report on Form 10-Q for additional details regarding our leases, convertible senior notes, and purchase commitments.

Off-balance sheet arrangements

We have not entered into any off-balance sheet arrangements.

Recent accounting pronouncements

See "Recent accounting pronouncements" in Note 2, "Summary of significant accounting policies" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1. of this Quarterly Report on Form 10-Q for a discussion of recently adopted accounting pronouncements and accounting pronouncements not yet adopted, and their expected effect on our financial position and results of operations.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. Our cash, cash equivalents, restricted cash and marketable securities totaled \$388.7 million at March 31, 2023, and consisted primarily of bank deposits, money market funds, U.S. treasury notes, and U.S. government agency securities. Such interest-bearing instruments carry a degree of risk; however, because our investments are primarily high-quality credit instruments with short-term durations with high-quality institutions, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. At March 31, 2023, a hypothetical 1.0% (100 basis points) increase or decrease in interest rates would not have resulted in a material change in the fair value of our cash equivalents and marketable securities. Fluctuations in the value of our cash equivalents and marketable securities caused by a change in interest rates (gains or losses on the carrying value) are recorded in other comprehensive (loss) income and are realized if we sell the underlying securities prior to maturity.

In February 2023, we repaid our 2020 Term Loan including the principal balance outstanding of \$135.0 million plus accrued interest of \$2.6 million. We did not use interest rate derivative instruments to manage our exposure to interest rate fluctuations related to our 2020 Term Loan prior to repayment.

Although our convertible senior notes are based on a fixed rate, changes in interest rates could impact their fair market value. As of March 31, 2023, the fair market value of the 2024 Notes and 2028 Notes was \$38.9 million and \$492.4 million, respectively. We elected the fair value option to account for the Senior Secured 2028 Notes, which requires the notes to be remeasured at estimated fair value as of each reporting date. Under the fair value election, we will record changes in fair value, inclusive of related accrued interest, through the condensed consolidated statement of operations as a fair value adjustment of the Senior Secured 2028 Notes each reporting period, with the portion of the change that results from a change in the instrument-specific credit risk recorded separately in other comprehensive income, if applicable. Fluctuations and volatility of our stock price can significantly affect the estimated fair value of the Senior Secured 2028 Notes and the corresponding change in fair value as of each reporting period. For additional information about the convertible senior notes, see Note 6, "Fair value measurements" and Note 7, "Commitments and contingencies" in Notes to Condensed Consolidated Financial Statements in Part I, Item 1. of this Quarterly Report on Form 10-Q.

ITEM 4. Controls and Procedures

(a) Evaluation of disclosure controls and procedures

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission ("SEC") rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer) have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) Changes in internal control over financial reporting

During the quarterly period covered by this Quarterly Report on Form 10-Q, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — Other Information

ITEM 1. Legal Proceedings.

For discussion of legal matters as of March 31, 2023, see Note 7, "Commitments and contingencies" in Notes to Condensed Consolidated Financial Statements in Part I, Item 1. of this Quarterly Report on Form 10-Q, which is incorporated to this item by reference.

ITEM 1A. Risk Factors

Risks related to our business and strategy

We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.

We have incurred substantial losses since our inception. For the three months ended March 31, 2023 and 2022, we had net losses of \$192.2 million and \$181.9 million, respectively. For the years ended December 31, 2022, 2021 and 2020, our net losses were \$3.1 billion, \$379.0 million and \$602.2 million, respectively. At March 31, 2023, our accumulated deficit was \$5.0 billion. We expect to continue to incur significant losses as we invest in our business. We incurred research and development expenses of \$62.0 million and \$128.2 million for the three months ended March 31, 2023 and 2022, respectively, and selling and marketing expenses of \$44.5 million and \$60.1 million for the three months ended March 31, 2023 and 2022, respectively. We incurred research and development expenses of \$402.1 million, \$416.1 million and \$240.6 million in 2022, 2021 and 2020, respectively, and selling and marketing expenses of \$218.9 million, \$225.9 million and \$168.3 million in 2022, 2021 and 2020, respectively. Since 2021, widespread inflationary pressures were experienced across global economies, resulting in higher costs for our raw materials, non-material costs, labor and other business costs, and significant increases in the future could adversely affect our results of operations. In addition, as a result of the integration of acquired businesses, we may be subject to unforeseen or additional expenditures, costs or liabilities, including costs and potential liabilities associated with litigation. Our prior losses and expected future losses have had and may continue to have an adverse effect on our stockholders' equity, working capital and stock price. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We began operations in January 2010 and commercially launched our initial assay in late November 2013. Our prospects must be considered in light of the risks and difficulties frequently encountered by companies in a similar stage of development, particularly companies in new and rapidly evolving markets such as ours. These risks include an evolving and unpredictable business model and the management of growth. To address these risks, we must, among other things, increase our customer base; continue to implement and successfully execute our business and marketing strategy; successfully enter into other strategic collaborations or relationships; obtain access to capital on acceptable terms and effectively utilize that capital; identify, attract, hire, retain, motivate and successfully integrate employees; continue to expand, automate and upgrade our laboratory, technology and data systems; obtain, maintain and expand coverage and reimbursement by healthcare payers; obtain and maintain sufficient payment by partners, institutions and individuals; provide rapid test turnaround times with accurate results at low prices; provide superior customer service; and respond to competitive developments. We cannot assure you that we will be successful in addressing these risks, and the failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.

We expect we will need to raise additional capital to finance operations prior to achieving profitability, or should we make additional acquisitions. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. In addition, the terms of our credit agreement restrict our ability to incur certain indebtedness and issue certain equity securities. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings, if available, could impose significant restrictions on our operations.

The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability

to incur additional debt or issue additional equity, limitations on our ability to acquire companies or acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, selling and marketing initiatives, or potential acquisitions. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to our company.

Our strategic realignment and the associated headcount reduction have and are expected to significantly change our business, result in significant expense, may not result in anticipated savings, and will disrupt our business.

On July 18, 2022, we initiated a strategic realignment of our operations and began implementing programs to reduce operating costs and drive future growth aligned with our core genetic testing and data platform and patient network. This realignment involves a significant reduction in our workforce as well as other steps to streamline our operations, including exiting our distributed products business and significantly decreasing our global footprint outside of the United States to less than a dozen countries or territories. Management currently expects that the strategic realignment will be completed in 2023 and estimates that the total costs incurred may be up to \$170 million for associated employee severance and benefits, losses on disposal of long-lived assets, and other restructuring costs including the write-off of prepaid assets related to the exit of certain product offerings, professional service fees and contract exit costs. Actual costs may be higher than we expect. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our realignment efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. For example, our divestiture activities may divert management's attention from our core business operations, result in significant write-offs and other charges, and have an adverse effect on existing relationships with partners, customers, patients and third-party payers. We have also terminated early, changed the scope of, or may not be able to perform under certain contracts as a result of our realignment efforts, and we could incur significant liability if we do not successfully negotiate wind-down provisions or new terms. For example, we have informed certain contractual counterparties that we will not be able to perform under our companion diagnostic development agreements. Any of these or other events could adversely affect our financial condition and results of operations. In addition, we may not be able to retain qualified personnel, which may negatively affect our infrastructure and operations or result in a loss of employees and reduced productivity among remaining employees. For example, our turnaround times in returning test results increased recently. Further, the realignment may yield unintended consequences, such as attrition beyond our intended workforce reduction, reduced employee morale, loss of customers or partners, and other adverse effects on our business.

If our management is unable to successfully manage this transition and realignment activities, our expenses may be more than expected and may vary significant from period to period and we may be unable to implement our business strategy. As a result, our future financial performance, operations, and prospects would be negatively affected.

We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.

Our performance, including our research and development programs and laboratory operations, largely depend on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization, including software developers, geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel to process and interpret our genetic tests. In addition, we may need to continue to expand our sales force with qualified and experienced personnel. In July 2022, we initiated a strategic realignment of our operations and began implementing cost reduction programs that will ultimately reduce our workforce by approximately 1,000 employees. This reduction in workforce has and will continue to result in the loss of institutional knowledge and expertise and the reallocation of and combination of certain roles and responsibilities across the

organization, all of which could adversely affect our operations. Further, the realignment has and may continue to yield unintended consequences, such as attrition beyond our intended workforce reduction and reduced employee morale. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. If the value of our common stock declines significantly, and remains depressed, as it has in the recent past, or if we do not have enough shares authorized to grant equity awards to new and existing employees, we may not be able to recruit and retain qualified employees. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to scale our business and support our research and development efforts and our clinical laboratory. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows and evolves, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

If third-party payers, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.

Our ability to increase the number of billable tests and our revenue will depend on our success achieving reimbursement for our tests from third-party payers. Reimbursement by a payer may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary, and cost-effective, and/or whether the patient has received prior authorization.

Since each payer makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payer to cover and the amount it will reimburse for our tests will likely be made on an indication-by-indication basis. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our germline tests from most of the large commercial third-party payers in the United States, and the Centers for Medicare & Medicaid Services, or CMS, provides reimbursement for our multi-gene tests for hereditary breast and ovarian cancer-related disorders as well as colon cancer. We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from third-party payers may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive and may not result in payment. In cases where there is not a contracted rate for reimbursement, there is typically a greater coinsurance or copayment requirement from the patient, which may result in further delay or decreased likelihood of collection.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payer to payer, and we have needed additional time and resources to comply with them. We have also experienced, and may continue to experience, delays in or denials of coverage if we do not adequately comply with these requirements. Our third-party payers have also requested, and in the future may request, audits of the amounts paid to us. We have been required to repay certain amounts to payers as a result of such audits, and we could be adversely affected if we are required to repay other payers for alleged overpayments due to lack of compliance with their reimbursement policies. In addition, we have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests and any future tests we may develop or acquire. If we fail to expand and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

We need to scale our infrastructure in advance of demand for our tests and other services, and our failure to generate sufficient demand for our tests and other services would have a negative impact on our business and our ability to attain profitability.

Our success depends in large part on our ability to extend our market position, to develop new services, to provide customers with high-quality test reports quickly and at a lower price than our competitors, and to achieve sufficient test volume to realize economies of scale. In order to execute our business model, we intend to continue to invest heavily in order to significantly scale our infrastructure, including our testing capacity and information

systems, expand our commercial operations, customer service, billing and systems processes and enhance our internal quality assurance program. We expect that much of this infrastructure growth will be in advance of demand for our tests and other services. Many of our current and future expense levels are fixed. Because the timing and amount of revenue from our services is difficult to forecast, when revenue does not meet our expectations, we may not be able to adjust our spending promptly or reduce our spending to levels commensurate with our revenue. Even if we are able to successfully scale our infrastructure and operations, we cannot assure you that demand for our services will increase at levels consistent with the growth of our infrastructure. If we fail to generate demand commensurate with this growth or if we fail to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition and results of operations could be adversely affected.

The global macroeconomic environment could negatively impact our business, our financial position and our results of operations.

Adverse macroeconomic developments, including inflation, slowing growth, rising interest rates, or recession, may adversely affect our business and financial condition. These developments have caused, and could in the future cause, disruptions and volatility in global financial markets and increased rates of default and bankruptcy, and negatively affect business and consumer spending. Adverse economic conditions have and may continue to increase the costs of operating our business, including vendor, supplier and workforce expenses, and may limit our access to capital or may significantly increase our cost of capital. Management continues to evaluate the impact of macroeconomic events, including inflation, on our business and our future plans and intends to take appropriate measures to help alleviate their impact, but there can be no assurance that these efforts will be successful. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. A severe or prolonged economic downturn, such as the global financial crisis, could also reduce our ability to raise additional capital when needed on acceptable terms, if at all. Presently, we have customers who have been adversely affected by Russia's invasion of Ukraine, and we have experienced some disruption in our engineering productivity as we have sought to assist contractors in both Ukraine and Russia who have been dislocated or who have chosen to flee Russia. Likewise, the capital and credit markets have been and may continue to be adversely affected by the invasion, the possibility of a wider European or global conflict, and global sanctions imposed in response to the invasion. We cannot predict the future trajectory of these risks, including how the macroeconomic environment will evolve or how it will continue to impact us.

Specifically, difficult macroeconomic conditions, such as cost inflation, decreases in per capita income and level of disposable income, increased and prolonged unemployment or a decline in consumer confidence as a result of COVID-19 or otherwise, as well as limited or significantly reduced points of access of our tests, could have a material adverse effect on the demand for our tests. Under difficult economic conditions, consumers may seek to reduce discretionary spending by forgoing our tests. Decreased demand for our tests, particularly in the United States, has negatively affected and could continue to negatively affect our overall financial performance.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, Silicon Valley Bank ("SVB"), Signature Bank and Silvergate Capital Corp. were each placed into receivership in March 2023. In addition, on May 1, 2023, the Federal Deposit Insurance Corporation ("FDIC") seized First Republic Bank and sold its assets to JPMorgan Chase & Co. Widespread demands for customer withdrawals or other liquidity demands may exceed other banks' access to cash and similarly be placed into receivership or sold. Additionally, it is uncertain whether the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

While we have not experienced any material impact to our liquidity or to our current and projected business operations, financial condition or results of operations as a result of these matters, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners or industry as a whole may be adversely impacted in ways that we cannot predict at this time.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations

under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceed the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of amounts held in excess of such insurance limitations. As noted above, the FDIC recently took control of SVB, Signature Bank, Silvergate Capital Corp and First Republic Bank. While we did have an account at SVB, our deposits were not affected as a result of such change. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

We hold a significant amount of marketable securities in U.S. treasury notes and U.S. government agency securities.

At March 31, 2023 and December 31, 2022, we had \$171.2 million and \$267.5 million, respectively, of cash, cash equivalents, and restricted cash and marketable securities of \$217.5 million and \$289.6 million, respectively. Our marketable securities are held primarily in the form of U.S. treasury notes and U.S. government agency securities. The current statutory limit on U.S. debt, commonly known as the debt ceiling, of \$31.4 trillion was reached in January, requiring the Treasury Department to take accounting measures to continue normally financing U.S. government obligations while avoiding exceeding the debt ceiling. It is expected, however, the U.S. government will exhaust these measures by June 2023. If the debt ceiling is not raised, the U.S. government may not be able to fulfill its funding obligations and there could be significant disruption to all discretionary programs and wider financial and economic repercussions. In addition, the value of our marketable securities could decline.

We face risks related to health epidemics, including the ongoing COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

Our business has been and could continue to be adversely affected by a widespread outbreak of contagious disease, including the COVID-19 pandemic. Global health concerns relating to COVID-19 have negatively affected the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. As discussed in our prior and current Form 10-K and 10-Q filings, our operations have been and will continue to be impacted by the COVID-19 pandemic and its related economic challenges. Even after COVID-19 has subsided, we may continue to experience an adverse impact to our business as a result of its global economic impact, including any recession that has occurred or may occur in the future.

There are no comparable recent events which may provide guidance as to the effect of the spread of COVID-19, and, as a result, the ultimate impact of COVID-19 or a similar health epidemic is highly uncertain and subject to change.

We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the markets in which we operate. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.

With the development of next generation sequencing, the clinical genetics market is becoming increasingly competitive, and we expect this competition to intensify in the future. We face competition from a variety of sources, including:

- dozens of relatively specialized competitors focused on genetics applied to healthcare, such as Ambry Genetics Corporation, a subsidiary of Realm IDx.; Athena Diagnostics, Inc. and Blueprint Genetics, subsidiaries of Quest Diagnostics Incorporated ("Quest Diagnostics"); Baylor-Miraca Genetics Laboratories LLC; Caris Life Sciences, Inc.; Centogene AG; Color Health, Inc.; Connective Tissue Gene Test LLC, a subsidiary of Health Network Laboratories, L.P.; Cooper Surgical, Inc.; Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Foundation Medicine, Inc., a subsidiary of Roche Holding AG; Fulgent Genetics, Inc.; Guardant Health, Inc.; Integrated Genetics, Sequenom Inc., Correlagen Diagnostics, Inc., and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings ("Labcorp"); Myriad Genetics, Inc.; Natera, Inc. ("Natera"); Perkin-Elmer, Inc.; and Sema4 Genomics; as well as other commercial and academic laboratories;
- a few large, established general testing companies with large market share and significant channel power, such as Labcorp and Quest Diagnostics;
- a large number of clinical laboratories in an academic or healthcare provider setting that perform clinical genetic testing on behalf of their affiliated institutions and often sell and market more broadly; and
- a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness including Illumina, Inc. ("Illumina"), which is also one of our suppliers.

Hospitals, academic medical centers and eventually physician practice groups and individual clinicians may also seek to perform at their own facilities the type of genetic testing we would otherwise perform for them. In this regard, continued development of equipment, reagents, and other materials as well as databases and interpretation services may enable broader direct participation in genetic testing and analysis.

Participants in closely related markets such as clinical trial or companion diagnostic testing could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide such potential competitors with significant advantages.

In addition, the biotechnology and genetic testing fields are intensely competitive both in terms of service and price, and continue to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

We also face competition as a result of our 2021 acquisition of Ciitizen Corporation ("Ciitizen"). Ciitizen competes with companies in the patient data platform business, including, among others, PicnicHealth, All Stripes Research Inc., Seqster PDM, Inc., Apple Inc. ("Apple"), Flatiron Health, Inc.

We believe the principal competitive factors in our market are:

- breadth and depth of content;
- quality;
- reliability;
- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;
- convenience of testing;
- brand recognition of test provider;
- additional value-added services and informatics tools;

- client service; and
- quality of website content.

Many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, higher margins on their tests, substantially greater financial, technological and research and development resources, selling and marketing capabilities, lobbying efforts, and more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do, sell their tests at prices designed to win significant levels of market share, or obtain reimbursement from more third-party payers and at higher prices than we do. We may not be able to compete effectively against these organizations. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payers are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies as use of next generation sequencing for clinical diagnosis and preventative care increases. Certain of our competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to website and systems development than we can. In the past, our competitors have been successful in recruiting our employees and may continue to recruit qualified employees from us. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. Some of our competitors have obtained approval or clearance for certain of their tests from the FDA. If payers decide to reimburse only for tests that are FDA-approved or FDA-cleared, or if they are more likely to reimburse for such tests, we may not be able to compete effectively unless we obtain similar approval or clearance for our tests. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

The market for patient data software is competitive, and our business will be adversely affected if we are unable to successfully compete.

The market for patient data software is competitive. Other than product innovation and access to healthcare data, there are no substantial barriers to entry in this market, and established or new entities may enter this market in the future. While software internally developed by enterprises represents indirect competition, we also compete directly with packaged application software vendors. In addition, we face actual or potential competition from larger companies such as Apple, and similar companies that may attempt to sell customer engagement software to their installed base.

We believe competition will continue to be substantial as current competitors increase the sophistication of their offerings and as new participants enter the market. Many of our current and potential competitors have longer operating histories, larger customer bases, broader brand recognition, and significantly greater financial, marketing and other resources. With more established and better-financed competitors, these companies may be able to undertake more extensive marketing campaigns, adopt more aggressive pricing policies, and make more attractive offers to businesses to induce them to use their products or services. If we are unable to compete successfully, our business will be adversely affected.

Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including protected health information, or PHI, personally identifiable information, genetic information, credit card information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive patient data through our various customer tools and platforms. In addition to storing and transmitting sensitive data that is subject to multiple legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with our data and

systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, viruses, security attacks, ransomware fraud, spikes in customer usage and denial of service issues. There continues to be a significant level of ransomware and cyber security attacks related to the ongoing conflict between Russia and Ukraine, which could result in substantial harm to internal systems necessary for running our critical operations and revenue generating services.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take what we believe to be reasonable and appropriate measures, including a formal, dedicated enterprise security program, to protect sensitive information from various compromises (including unauthorized access, disclosure, or modification or lack of availability), our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. For example, we have been subject to phishing incidents in the past, and we may experience additional incidents in the future. Any such breach or interruption could compromise our networks, and the information stored therein could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen.

Unauthorized access, loss or dissemination could also disrupt our operations including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

In addition to data security risks, we face privacy risks. Should we actually violate, or be perceived to have violated, any privacy commitments we make to patients or consumers, we could be subject to a complaint from an affected individual or interested privacy regulator, such as the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR), the FTC, a state Attorney General, an EU Member State Data Protection Authority, or a data protection authority in another international jurisdiction. This risk is heightened given the sensitivity of the data we collect.

Any security compromise that causes an apparent privacy violation could also result in legal claims or proceedings and liability and penalties under federal, state, foreign, or multinational laws that regulate the privacy, security, or breach of personal information, such as but not limited to HIPAA, HITECH, the FTC Act, state UDAP data security and data breach notification laws, the GDPR and the UK Data Protection Act of 2018.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. The GDPR took effect in May 2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. Among other requirements, the GDPR imposes strict rules on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, which includes sensitive information such as health and genetic information of data subjects. Maximum penalties for violations of the GDPR are capped at 20.0 million euros or 4% of an organization's annual global revenue, whichever is greater.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, in June 2018, California adopted the California Consumer Privacy Act of 2018, or the CCPA. The CCPA, is a comprehensive consumer privacy law that took effect in January 2020 and was further amended as of January 1, 2023. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of natural persons who reside in California. The CCPA does not apply to personal information that is PHI under HIPAA. The CCPA also does not apply to a HIPAA-regulated entity to the extent that the entity maintains patient information in the same manner as PHI. In addition, de-identified data as defined under HIPAA is also exempt from the CCPA. Accordingly, we do not have CCPA compliance obligations with respect to most genetic testing and patient information we collect and process. However, we are required to comply with the CCPA insofar as we collect other categories of California consumers' personal information.

Several other states in the United States have either recently enacted or are currently considering similar consumer data privacy laws, which could impact our operations if enacted. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business, results of operations, and financial condition.

It is possible the GDPR, CCPA and other emerging United States and international data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy laws and regulations may differ from country to country and state to state, and our obligations under these laws and regulations vary based on the nature of our activities in the particular jurisdiction, such as whether we collect samples from individuals in the local jurisdiction, perform testing in the local jurisdiction, or process personal information regarding employees or other individuals in the local jurisdiction. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We can provide no assurance that we are or will remain in compliance with diverse privacy and data security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and data security requirements could result in a variety of consequences, including civil or criminal penalties, litigation, or damage to our reputation, any of which could have a material adverse effect on our business.

If we are not able to continue to generate substantial demand for our tests, our commercial success will be negatively affected.

Our business model assumes that we will be able to generate significant test volume, and we may not succeed in continuing to drive adoption of our tests to achieve sufficient volumes. Inasmuch as detailed genetic data from broad-based testing panels such as our tests have only recently become available at relatively affordable prices, the continued pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes. Given the substantial amount of additional information available from a broad-based testing panel such as ours, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate further demand for our tests, we will need to continue to make clinicians aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. A lack of or delay in clinical acceptance of broad-based panels such as our tests would negatively impact sales and market acceptance of our tests and limit our revenue growth and potential profitability. Genetic testing can be expensive and many potential customers may be sensitive to pricing. In addition, potential customers may not adopt our tests if adequate reimbursement is not available, or if we are not able to maintain low prices relative to our competitors. Also, we may not be successful in increasing demand for our tests through our direct channel, in which we facilitate the ordering of our genetic tests by consumers through an online network of physicians.

If we are not able to generate demand for our tests at sufficient volume, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition and results of operations could be materially harmed.

We have devoted a portion of our resources to research and development activities related to our Personalized Cancer Monitoring, or PCM, service for cancer monitoring. The demand for this service is unproven, and we may not be successful in achieving market awareness and demand for these services through our sales and marketing operations.

Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.

Our success depends on our ability to provide reliable, high-quality tests that incorporate rapidly evolving information about the role of genes and gene variants in disease and clinically relevant outcomes associated with those variants. Errors, such as failure to detect genomic variants with high accuracy, or mistakes, such as failure to identify, or incompletely or incorrectly identifying, gene variants or their significance, could have a significant adverse impact on our business.

Hundreds of genes can be implicated in some disorders, and overlapping networks of genes and symptoms can be implicated in multiple conditions. As a result, a substantial amount of judgment is required in order to interpret testing results for an individual patient and to develop an appropriate patient report. We classify variants in accordance with published guidelines as benign, likely benign, variants of uncertain significance, likely pathogenic or pathogenic, and these guidelines are subject to change. In addition, it is our practice to offer support to clinicians and geneticists ordering our tests regarding which genes or panels to order as well as interpretation of genetic

variants. We also rely on clinicians to interpret what we report and to incorporate specific information about an individual patient into the physician's treatment decision.

The marketing, sale and use of our genetic tests could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on, information we provide to clinicians, geneticists or patients, and has led and may lead to claims against us if someone were to allege that a test failed to perform as it was designed, if we failed to correctly interpret the test results, if we failed to update the test results due to a reclassification of the variants according to new published guidelines, or if the ordering physician were to misinterpret test results or improperly rely on them when making a clinical decision. In addition, our entry into the reproductive health and pharmacogenetic testing markets expose us to increased liability. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain liability insurance, including for errors and omissions, we cannot assure you that such insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests. The occurrence of any of these events could have an adverse effect on our reputation and results of operations.

Our industry is subject to rapidly changing technology and new and increasing amounts of scientific data related to genes and genetic variants and their role in disease. Our failure to develop tests to keep pace with these changes could make us obsolete.

In recent years, there have been numerous advances in methods used to analyze very large amounts of genomic information and the role of genetics and gene variants in disease and treatment therapies. Our industry has and will continue to be characterized by rapid technological change, increasingly larger amounts of data, frequent new testing service introductions and evolving industry standards, all of which could make our tests obsolete. Our future success will also depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. Our tests could become obsolete and our business adversely affected unless we continually update our offerings to reflect new scientific knowledge about genes and genetic variations and their role in diseases and treatment therapies.

Our success will depend in part on our ability to generate sales using our internal sales team and through alternative marketing strategies.

We may not be able to market or sell our current tests and any future tests we may develop or acquire effectively enough to drive demand sufficient to support our planned growth. We currently sell our tests primarily through our internal sales force. Historically, our sales efforts have been focused primarily on hereditary cancer and more recently on reproductive health. Our efforts to sell our tests to clinicians and patients outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. In addition to the efforts of our sales force, future sales will depend in large part on our ability to develop and substantially expand awareness of our company and our tests through alternative strategies including through education of key opinion leaders, through social media-related and online outreach, education and marketing efforts, and through focused channel partner strategies designed to drive demand for our tests. We also may continue to spend on consumer advertising in connection with our direct channel to consumers, which could be costly. We have limited experience implementing these types of marketing efforts. We may not be able to drive sufficient levels of revenue using these sales and marketing methods and strategies necessary to support our planned growth, and our failure to do so could limit our revenue and potential profitability.

We also use a limited number of distributors to assist internationally with sales, logistics, education and customer support. Sales practices utilized by our distributors that are locally acceptable may not comply with sales practices standards required under U.S. laws that apply to us, which could create additional compliance risk. If our sales and marketing efforts are not successful outside the United States, we may not achieve significant market acceptance for our tests outside the United States, which could adversely impact our business.

Impairment in the value of our intangible assets has and may in the future have a material adverse effect on our operating results and financial condition.

We record intangible assets at fair value upon the acquisition of a business. Indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a

reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of our reporting unit has and may in the future result in an impairment of intangible assets and, in turn, a charge to net income.

We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments, materials and services, and we may not be able to find replacements or immediately transition to alternative suppliers.

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Illumina, Integrated DNA Technologies Incorporated, QIAGEN N.V., Roche Holdings Ltd. and Twist Bioscience Corporation for certain laboratory substances used in the chemical reactions incorporated into our processes, which we refer to as reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We do not have short- or long-term agreements with most of our suppliers, and our suppliers could cease supplying these materials and equipment at any time, or fail to provide us with sufficient quantities of materials or materials that meet our specifications. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations could impact our supply chain and laboratory operations as well as our ability to conduct our tests, and it could take a substantial amount of time to integrate replacement equipment into our laboratory operations.

We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot assure you that we will be able to secure alternative equipment, reagents and other materials, and bring such equipment, reagents and materials online and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, we cannot assure you that replacement sequencers and associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business, financial condition, results of operations and reputation could be adversely affected.

We depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process and drug metabolism, our patient data platform, our clinical report optimization systems, our customer-facing web-based software, our customer reporting, and our various customer tools and platforms. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, customer relationship management, regulatory compliance and other infrastructure operations. In addition, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design, and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, and general administrative activities, including financial reporting.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to

clinicians, billing payers, processing reimbursement appeals, handling physician or patient inquiries, conducting research and development activities, and managing the administrative and financial aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and results of operations.

Technical problems have arisen, and may arise in the future, in connection with our data and systems, including those that are hosted by third-party providers, which have in the past and may in the future result in interruptions in our business and operations. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

If our laboratories or other facilities become inoperable due to disasters, health epidemics or for any other reasons, we will be unable to perform our tests and our business will be harmed.

We perform all of our tests at our production facilities in San Francisco, California, in Iselin, New Jersey, and in Seattle, Washington. We also plan to open a new laboratory and production facility in Morrisville, North Carolina. Our laboratories and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use. Our laboratories may be harmed or rendered inoperable or inaccessible due to natural or man-made disasters, including earthquakes, hurricanes, flooding, fire and power outages, or by health epidemics, such as the COVID-19 pandemic, which may render it difficult or impossible for us to perform our tests for some period of time. This risk of natural disaster is especially high for us since we perform the majority of our tests at our San Francisco laboratory, which is located in an active seismic region, and we do not have a redundant facility to perform the same tests in the event our San Francisco laboratory is inoperable. The inability to perform our tests or the backlog that could develop if our laboratories are inoperable for even a short period of time may result in the loss of customers or harm our reputation. If a natural disaster were to damage one of our facilities significantly or if other events were to cause our operations to fail or be significantly curtailed, we may be unable to provide our services, or develop new services. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all. The inability to open the planned facility in North Carolina, delays in opening such facility or failure to obtain required permits, licenses, or certifications could result in increased costs and prevent us from realizing the intended benefits of the new facility.

Development of new tests is a complex process, and we may be unable to commercialize new tests on a timely basis, or at all.

We cannot assure you that we will be able to develop and commercialize new tests on a timely basis. Before we can commercialize any new tests, we will need to expend significant funds in order to:

- conduct research and development;
- further develop and scale our laboratory processes; and
- further develop and scale our infrastructure to be able to analyze increasingly larger and more diverse amounts of data.

Our testing service development process involves risk, and development efforts may fail for many reasons, including:

- failure of any test to perform as expected;
- lack of validation or reference data; or
- failure to demonstrate utility of a test.

As we develop tests, we will have to make significant investments in development, marketing and selling resources. In addition, competitors may develop and commercialize competing tests faster than we are able to do so.

Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests.

Genetic testing has raised ethical, legal and social issues regarding privacy rights and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of

genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genomic tests even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests, either of which could have an adverse effect on our business, financial condition or results of operations.

We have acquired and may continue to acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.

As part of our business strategy, we have pursued and expect to continue to evaluate acquisitions of complementary businesses or assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. Since 2017, we have acquired numerous companies.

With respect to our acquired businesses and any acquisitions we may make in the future, we may not be able to integrate these businesses successfully into our existing business, and we could assume unknown or contingent liabilities. Acquisitions by us have, and may in the future, result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Furthermore, as we experienced in the past, the loss of customers, payers, partners, suppliers or key management following the completion of any acquisitions by us could harm our business. In addition, as part of our strategic realignment, we have and may continue to divest assets acquired in previous acquisitions at substantial discounts to the price we paid, or without realizing the benefits we intended at the time of the acquisition. Changes in services, sources of revenue, and branding or rebranding initiatives may involve substantial costs and may not be favorably received by customers, resulting in an adverse impact on our financial results, financial condition and stock price. Integration of an acquired company or business also may require management's time and resources that otherwise would be available for ongoing development of our existing business. We may also need to divert cash from other uses to fund these integration activities and these new businesses. Ultimately, we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment, or these benefits may take longer to realize than we expected.

In connection with certain of our completed acquisitions, we have agreed to pay cash and/or stock consideration that is contingent upon the achievement of specified objectives, such as development objectives, regulatory submissions, regulatory approvals and revenue related to certain products. As of the date of the applicable acquisition, we record a contingent liability representing the estimated fair value of the contingent consideration we expect to pay. On a quarterly basis, we reassess these obligations and, in the event our estimate of the fair value of the contingent consideration changes, we record increases or decreases in the fair value as an adjustment to operating expense, which could have a material impact on our results of operations. In addition, in connection with our strategic realignment, we have recently divested or sublicensed certain product offerings, technologies and assets that we had acquired in prior years.

To finance any acquisitions or investments, we may raise additional funds, which could adversely affect our existing stockholders and our business. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. In addition, our stockholders may experience substantial dilution as a result of additional securities we may issue for acquisitions. Open market sales of substantial amounts of our common stock issued to stockholders of companies we acquire could also depress our stock price. Additional funds may not be available on terms that are favorable to us, or at all.

Our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;

- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- logistics and regulations associated with shipping samples, including infrastructure conditions, customs and transportation delays;
- limits on our ability to penetrate international markets if we do not to conduct our tests locally;
- natural disasters and outbreaks of disease, including the ongoing COVID-19 pandemic;
- political and economic instability, including wars such as the current conflict in Ukraine, terrorism and political unrest, boycotts, curtailment of trade, government sanctions and other business restrictions;
- inflationary pressures, such as those the global market is currently experiencing, which have and may increase costs for materials, supplies, and services; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our international operations and, consequently, our revenue and results of operations.

In addition, applicable export or import laws and regulations such as prohibitions on the export of samples imposed by countries outside of the United States, or international privacy or data restrictions that are different or more stringent than those of the United States, may require that we build additional laboratories or engage in joint ventures or other business partnerships in order to offer our tests internationally in the future. Any such restrictions would impair our ability to offer our tests in such countries and could have an adverse effect on our business, financial condition and results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of March 31, 2023, we have substantial deferred tax assets consisting of federal and state net operating losses and tax credit carryforwards. At December 31, 2022, our total gross deferred tax assets were \$795.5 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, our net deferred tax assets have been fully offset by a valuation allowance. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% stockholders” that exceeds 50 percentage points over a rolling three-year period. Some of our prior acquisitions have resulted in an ownership change, and we may experience ownership changes in the future. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, or other future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. In addition, the Tax Cuts and Jobs Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Also, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks related to our indebtedness

The terms of our convertible senior secured notes will require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In February 2023, we issued \$305.3 million aggregate principal amount of our 4.50% convertible senior secured notes due 2028, or the convertible senior secured notes. The convertible senior secured notes are secured

by a first priority lien on substantially all of our and our subsidiaries' assets (including our intellectual property) and are guaranteed by our subsidiaries, in each case, excluding certain excluded assets and immaterial subsidiaries.

The indenture governing our convertible senior secured notes restricts our ability to, among other restrictions, pursue certain dispositions, mergers or acquisitions, encumber our intellectual property, incur indebtedness or liens, pay dividends or make other payments in respect of our capital stock, make investments and engage in certain other business transactions. In addition, the indenture contains financial covenants that will require us to maintain revenue in the prior four quarters of not less than \$250.0 million and, starting with the quarter ending March 31, 2025, a minimum liquidity of at least 15% of the amount of our secured indebtedness then outstanding. If we fail to comply with these or any of the other covenants under the indenture and are unable to obtain a waiver or amendment, the holders of the convertible senior secured notes may, among other things, declare all of the convertible senior secured notes due and payable and exercise rights with respect to collateral securing those notes, each of which could significantly harm our business, financial condition and prospects and could cause the price of our common stock to decline.

If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

If our stockholders do not approve the conversion of the convertible senior secured notes, we may not have the cash necessary to settle such notes in cash upon conversion.

Our convertible senior secured notes will be convertible at any time at the option of the holders thereof, provided that the holders are prohibited from converting such notes into shares of common stock in excess of the limitations imposed by the rules of the NYSE prior to such time that we obtain stockholder approval for the issuance of such excess shares of common stock. In the absence of stockholder approval, we will be required, after the grace period specified under the indenture with respect to the convertible senior secured notes, to settle any conversion of the excess shares in cash at the then current fair market value, if the holders elect to convert. If we are unable to obtain the requisite stockholder approval and holders convert the convertible senior secured notes, we may not have sufficient cash to satisfy our obligations to the converting holders.

We have a large amount of debt, servicing our debt requires a significant amount of cash, we may not have sufficient cash flow from our business to service our debt, and we may need to refinance all or a significant portion of our debt.

As of March 31, 2023, we had outstanding \$44.3 million aggregate principal amount of our convertible senior notes due 2024, or the 2024 notes, \$1,150.0 million aggregate principal amount of our existing convertible senior notes due 2028, or the unsecured 2028 notes, and \$305.3 million aggregate principal amount of our new convertible senior secured notes due 2028. We refer to the 2024 notes and the unsecured 2028 notes as the unsecured convertible notes, and we refer to the unsecured convertible notes and the convertible senior secured notes collectively as the outstanding convertible notes.

Our substantial leverage could have significant negative consequences for our future operations, including:

- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financial for working capital, acquisitions, research and development expenditures, and general corporate purposes;
- requiring the dedication of a substantial portion of our cash flow or our existing cash to service our indebtedness, thereby reducing the amount of our cash available for other purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; or
- placing us at a possible competitive disadvantage compared to less leveraged competitors and competitors that have better access to capital resources.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt, including paying off the principal when due, and make necessary capital expenditures. The respective conversion prices of our unsecured convertible notes are significantly higher than the prevailing market prices for our common stock, and our stock price would have to increase significantly in order for holders to convert our notes prior to maturity. If we are unable to generate cash flow necessary to service or repay our debt at maturity,

we may be required to adopt one or more alternatives, including, but not limited to, selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time, and the terms of any such refinancing may be less favorable to us than the terms of our current indebtedness. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to repurchase our outstanding convertible notes upon a fundamental change or major transaction, as applicable, and the indenture governing our current senior secured notes contains, and our future debt may contain, limitations on our ability to pay cash to repurchase our outstanding convertible notes and other debt.

Holders of our outstanding unsecured convertible notes have the right to require us to repurchase all or any portion of their notes upon the occurrence of a fundamental change, as defined in the respective indentures governing our outstanding unsecured convertible notes, at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. The repurchase price for our unsecured 2028 notes will also include unpaid interest on such notes to the maturity date. Similarly, holders of our convertible senior secured notes will have the right to require us to repurchase all or any portion of their notes upon the occurrence of a major transaction, as defined in the indenture governing our convertible senior secured notes, for an amount equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest and a make whole amount as set forth in such indenture. The indenture governing our convertible senior secured notes will limit our ability to pay cash to repurchase our unsecured convertible notes, and we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of notes surrendered for repurchase. In addition, our ability to repurchase our outstanding convertible notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the respective indentures governing the notes would constitute a default under the relevant indentures. A default under an indenture or the occurrence of the fundamental change or major transaction itself could also lead to a default under the indentures governing our other convertible notes or any agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and to repay or repurchase our convertible notes.

The conditional conversion feature of our convertible senior notes due 2024, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of our convertible senior notes due 2024 is triggered, holders of such notes will be entitled to convert the notes at any time during specified periods at their option. If one or more holders elect to convert their notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

Risks related to government regulation

If the FDA regulates the tests we currently offer as LDTs as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.

We provide many of our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by CLIA, and state law, respectively).

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality system regulations, premarket clearance or premarket approval, and post-market controls). See Part I, Item 1. of our Annual Report on Form 10-K for the year ended December 31, 2022, under the heading "Regulation—Federal oversight of laboratory developed tests" for a description of applicable federal regulations, which is incorporated by reference herein.

If the FDA ultimately regulates certain LDTs whether via individualized enforcement action, more generally as outlined in final guidance or final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition and results of operations.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

If we fail to comply with federal, state and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of health of, human beings. CLIA regulations establish specific requirements and standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers, for our tests.

We are also required to maintain certain in-state and out-of-state laboratory licenses and approvals to conduct testing. For more information about our federal (CLIA) and state laboratory licenses and approvals, please see Part I, Item 1. of our Annual Report on Form 10-K for the year ended December 31, 2022, under the headings "Regulation—Clinical Laboratory Improvement Amendments of 1988, or CLIA" and "Regulation—State laboratory licensure requirements," which are incorporated by reference herein. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of samples necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays.

In order to eventually market certain of our current or future products and services in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding quality, safety, performance and efficacy. In addition, clinical trials or clinical investigations conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory clearance, authorization or approval in one country does not guarantee regulatory clearance, authorization or approval in any other country. For example, the performance characteristics of certain of our products and services may need to be validated separately in specific ethnic and genetic populations. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory clearance, authorization or approval could result in difficulties and costs for us and our collaborators and require additional preclinical studies, clinical trials or clinical investigations which could be costly and time-consuming. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of certain of our products and services in those countries. The foreign regulatory clearance, authorization or approval process involves all of the risks and uncertainties associated with FDA clearance, authorization or approval. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products and services will be unrealized.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, cancellation of the laboratory's approval to receive Medicare and Medicaid payment for its services, exclusion from some healthcare systems' programs, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certifications, a state or foreign

license, or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

The College of American Pathologists, or CAP, maintains a clinical laboratory accreditation program. CAP asserts that its program is “designed to go well beyond regulatory compliance” and helps laboratories achieve the highest standards of excellence to positively impact patient care. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. We have CAP accreditations for our laboratories. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- HIPAA and HITECH, which set forth comprehensive federal standards with respect to the privacy and security of protected health information, breach notification requirements, and requirements for the use of certain standardized electronic transactions;
- the GDPR, which imposes strict privacy and security requirements on controllers and processors of personal data, including enhanced protections for “special categories” of personal data, including sensitive information such as health and genetic information of data subjects;
- the CCPA and other, similar state consumer privacy laws, which, among other things, regulate how subject businesses may collect, use, and disclose the personal information of consumers in the regulated state, afford rights to consumers that they may exercise against businesses that collect their information, and require implementation of reasonable security measures to safeguard personal information of consumers;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or recommend purchasing, leasing or ordering, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;
- The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and reaches beyond federal health care programs, to include private insurance;
- the federal physician self-referral law, known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity unless an exception applies, and prohibits an entity from billing for designated health services furnished pursuant to a prohibited referral;
- the federal false claims law, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the HIPAA fraud and abuse provisions, which create new federal criminal statutes that prohibit, among other things, defrauding health care benefit programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or

discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;

- the 21st Century Cures Act information blocking prohibition, which prohibits covered actors from engaging in certain practices that are likely to interfere with the access, exchange, or use of electronic health information;
- the federal Physician Payments Sunshine Act, which requires reporting of certain payments and other transfers of value made by applicable manufacturers, directly or indirectly, to or on behalf of various healthcare professionals (including doctors, physician assistants, and nurse practitioners) and teaching hospitals, and requires reporting of certain ownership and investment interests held by physicians and their immediate family members as well as similar state laws that require reporting of information in addition to what is required under the federal Physician Payments Sunshine Act;
- state laws that limit or prohibit the provision of certain payments and other transfers of value to certain covered healthcare providers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payers; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance may also be subject to governmental review. The growth of our business and our operations outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. In October 2021, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting that we produce certain documents regarding our sponsored testing programs. We have produced documents and information in response to the subpoena and are cooperating fully with the investigation. Although we remain committed to compliance with all applicable laws and regulations, we cannot predict the outcome of this investigation or any other requests or investigations that may arise in the future regarding these or other subject matters. Any action brought against us for violation of the above-referenced or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in Federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Healthcare policy changes, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition, results of operations and cash flows.

In March 2010, the Affordable Care Act, was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Policy changes or implementation of new health care legislation could result in significant changes to health care systems. In the United States, this could include potential modification or repeal of all or parts of the Affordable Care Act.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, as amended, and its implementing regulations, clinical laboratories must report to CMS private payer rates beginning in 2017, and then in 2024 and every three years thereafter for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests and every year for advanced diagnostic laboratory tests.

We do not have "advanced diagnostic laboratory test" status for our tests, but in the event that we obtain designation for one or more of our tests as an advanced diagnostic laboratory test and the tests are determined by CMS to meet these criteria or new criteria developed by CMS, we would be required to report private payer data for those tests annually. Otherwise, we will be required to report private payer rates for our tests on an every three-

years basis starting in 2023. Laboratories that fail to timely report the required payment information may be subject to substantial civil money penalties.

See Part I, Item 1. of our Annual Report on Form 10-K for the year ended December 31, 2022, under the heading "Regulation—Reimbursement" for a description of how public and private payers pay for our products and services, which is incorporated by reference herein. Changes in these payments and the methodologies used to determine payment amounts could have a significant impact on our financial condition, results of operations and cash flows.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. For instance, the payment reductions imposed by the Affordable Care Act and the expansion of the federal and state governments' role in the U.S. healthcare industry as well as changes to the reimbursement amounts paid by payers for our tests and future tests or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would increase our billing and collecting costs and decrease our revenue.

If we use hazardous materials in a manner that causes injury, we could be liable for resulting damages.

Our activities currently require the use of hazardous chemicals and biological material. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. In 2018, we decommissioned our laboratory in Massachusetts; however, we could be held liable for any damages resulting from our prior use of hazardous chemicals and biological materials at this facility. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

We could be adversely affected by violations of the FCPA and other worldwide anti-bribery laws.

We are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We use a limited number of independent distributors to sell our tests internationally, which requires a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

Risks related to our intellectual property

One of our competitors has alleged that our Anchored Multiplex PCR, or AMP, chemistry and products using AMP are infringing on its intellectual property, and we may be required to redesign the technology, obtain a license, cease using the AMP chemistry altogether and/or pay significant damages, among other consequences, any of which would have a material adverse effect on our business as well as our financial condition and results of operations.

Our AMP chemistry is the foundation of our PCM service. One of our competitors, Natera, Inc., or Natera, has filed complaints against ArcherDX, Invitae and Genosity alleging that our products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe certain patents. A description of this

ongoing litigation is provided in Note 7, "Commitments and contingencies" in Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report.

If any of our products or our use of AMP chemistry is found to infringe any of Natera's patents, we could be required to redesign our technology or obtain a license from Natera to continue developing, manufacturing, marketing, selling and commercializing AMP and related products. However, we may not be successful in the redesign of its technology or able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving Natera and other third parties the right to use the same technologies licensed to us, and Natera could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to permanently cease developing, manufacturing, marketing and commercializing our products that are found to be infringing. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed Natera's asserted patents. Even if we were ultimately to prevail, litigation with Natera could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We cannot reasonably estimate the final outcome, including any potential liability or any range of potential future charges associated with these litigations. However, any finding of infringement by us of Natera's asserted patents could have a material adverse effect on our business, as well as our financial condition and results of operations.

Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation will require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price.

Our commercial success will depend in part on our avoiding infringement of patents and proprietary rights of third parties, including for example the intellectual property rights of competitors. As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests, and enter new markets, competitors might claim that our tests infringe or misappropriate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. Our activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. For example, as discussed in the preceding risk factor, we are currently engaged in litigation with a competitor of ArcherDX alleging infringement. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We may be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, regardless of merit, could cause us to incur substantial expenses and be a substantial diversion of our employee resources. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our business and stock price. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, possibly including treble damages and attorneys' fees if we are found to have willfully infringed patents; (2) obtain one or more licenses, which may not be available on commercially reasonable terms (if at all); (3) pay royalties; and/or (4) redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, all of which could have a material adverse impact on our cash position and business and financial condition.

If licenses to third-party intellectual property rights are or become required for us to engage in our business, we may be unable to obtain them at a reasonable cost, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in the introduction of tests while we attempt to develop alternatives. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing tests, which could materially affect our ability to grow and thus adversely affect our business and financial condition.

Developments in patent law could have a negative impact on our business.

Although we view current U.S. Supreme Court precedent to be aligned with our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts (such as patient genetic data) and an understanding of that fact's implications (such as a patient's risk of disease associated with certain genetic

variations) should not be patentable, it is possible that subsequent determinations by the U.S. Supreme Court or other federal courts could limit, alter or potentially overrule current law. Moreover, from time to time the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office, or USPTO, may change the standards of patentability, and any such changes could run contrary to, or otherwise be inconsistent with, our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts and an understanding of that fact's implications should not be patentable, which could result in third parties newly claiming that our business practices infringe patents drawn from categories of patents which we currently view to be invalid as directed to unpatentable subject matter. For example, on August 2, 2022, Senator Thom Tillis (R-NC) introduced a bill entitled The Patent Eligibility Restoration Act of 2022 that would overrule current U.S. Supreme Court precedent concerning the scope of patentable subject matter. If the proposed bill were to be enacted into law, there could be an increase in third-party claims to patent rights over correlations between patient genetic data and its interpretation and such third parties may assert that our business practices infringe some of those resulting patent rights.

Our inability to effectively protect our proprietary technologies, including the confidentiality of our trade secrets, could harm our competitive position.

We currently rely upon trade secret protection and copyright, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, and to a limited extent patent protection, to protect our confidential and proprietary information. Although our competitors have utilized and are expected to continue utilizing similar methods and have aggregated and are expected to continue to aggregate similar databases of genetic testing information, our success will depend upon our ability to develop proprietary methods and databases and to defend any advantages afforded to us by such methods and databases relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our methods and databases and thereby erode any competitive advantages we may have.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. In this regard, we have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, we expect that potential patent coverage we may obtain will not be sufficient to prevent substantial competition. In this regard, we believe it is probable that others will independently develop similar or alternative technologies or design around those technologies for which we may obtain patent protection. In addition, any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. Questions as to inventorship or ownership may also arise. Any finding that our patents or applications are unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, which would be expensive, and, if we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel.

We expect to rely primarily upon trade secrets and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. Among other things, we seek to protect our trade secrets and confidential information by entering into confidentiality agreements with employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees and consultants will provide meaningful protection for our trade secrets and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Accordingly, there also can be no assurance that our trade secrets will not otherwise become known or be independently developed by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In

addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

As an example, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system will likely be introduced by the end of 2023, which would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks related to being a public company

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and the NYSE, impose a number of requirements on public companies, including with respect to corporate governance practices. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In addition, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, enacted in 2010, includes significant corporate governance and executive-compensation-related provisions. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. If these requirements divert the attention of our management and personnel from other aspects of our business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, these rules and regulations applicable to public companies substantially increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time consuming and costly. It may also be more expensive for us to obtain director and officer liability insurance.

If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

We are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have compiled the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. As we acquire companies, we will need to establish adequate controls and integrate them into our internal control system. We need to maintain and enhance these processes and controls as we grow and we have required, and may continue to require, additional personnel and resources to do so.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal controls, our management will be unable to conclude that our internal control over financial reporting is effective. Our independent registered public accounting firm is required to issue an attestation report on the effectiveness of our internal control over financial reporting every fiscal year. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in the restatement of our financial results in the future.

General risk factors

Our stock price is volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

The trading price of our common stock is volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated fluctuations in our operating results;
- effects of our strategic realignment and workforce reduction and our ability to achieve the intended benefits of these activities;
- costs associated with our strategic realignment;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our stock;
- our substantial leverage and market perceptions regarding the same;
- the level of short interest in our stock, and the effect of short sellers on the price of our stock;
- actual or anticipated changes in regulatory oversight of our business;
- additions or departures of key management or other personnel;
- disputes or other developments related to our intellectual property or other proprietary rights, including litigation;
- changes in reimbursement by current or potential payers;
- general economic and market conditions; and

- issuances of significant amounts of our common stock.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. The closing price of our common stock on the NYSE ranged from \$1.20 to \$8.63 between May 2, 2022 through May 1, 2023. Broad market and industry factors, including the COVID-19 pandemic, as well as general economic, political and geopolitical, and market conditions such as recessions, wars such as the current conflict in Ukraine, elections, interest rate changes, or cost inflation, may seriously affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock, change their price targets, issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, the terms of our credit agreement restrict our ability to pay dividends. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 20,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our chair of the board or our chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum; and
- require a super-majority of votes to amend certain of the above-mentioned provisions as well as to amend our bylaws generally.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law; or
- any action asserting a claim against us governed by the internal affairs doctrine.

Section 27 of the Securities Exchange Act of 1934, or Exchange Act, creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 22 of the Securities Act of 1933, or Securities Act, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of March 31, 2023, we had outstanding 260.7 million shares of our common stock, options to purchase 2.3 million shares of our common stock (of which 1.2 million were exercisable as of that date) and outstanding restricted stock units, or RSUs, representing 11.0 million shares of our common stock (which includes an estimated number of RSUs, subject to certain employees' continued service with us, or time-based RSUs, and RSUs that are performance based RSUs, or PRSUs, granted in connection with an acquisition). The foregoing does not include 0.8 million shares of common stock that may be issuable in connection with indemnification hold-backs and contingent consideration related to our acquisitions, shares that may be issuable in the future in connection with the convertible senior notes, or shares issuable pursuant to our May 2021 sales agreement with Cowen and Company, LLC under which we may offer and sell from time to time at our sole discretion shares of our common stock in an aggregate amount not to exceed \$400 million. In addition, as of March 31, 2023, 15.8 million and 4.6 million shares of common stock are available for future issuance under our 2015 Stock Incentive Plan and Employee Stock Purchase Plan, respectively. The sale or the availability for sale of a large number of shares of our common stock in the public market could cause the price of our common stock to decline.

ITEM 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
2.1 [@]	Agreement and Plan of Merger and Plan of Reorganization, dated as of June 21, 2020, by and among Invitae Corporation, Apollo Merger Sub A Inc., Apollo Merger Sub B LLC, ArcherDX, Inc. and Kyle Lefkoff, solely in his capacity as holders' representative.	8-K	2.1	6/24/2020	
3.1	Amended and Restated Certificate of Incorporation of Invitae Corporation, as amended by the Certificate of Amendment to the Amended and Restated Certificate of Incorporation, dated June 8, 2022.				X
4.1	Form of Warrant to Purchase Shares of Common Stock of Invitae Corporation.	8-K	4.2	3/1/2023	
4.2	Indenture, dated as of March 7, 2023, between Invitae Corporation, the guarantor parties thereto and U.S. Bank Trust Company, National Association, as trustee and collateral agent.	8-K	4.1	3/8/2023	
4.3	Series A Global Note representing the Series A 4.50% Convertible Senior Secured Notes due 2028, dated as of March 7, 2023, between Invitae Corporation and U.S. Bank Trust Company, National Association, as trustee.	8-K	4.2	3/8/2023	
4.4	Series B Global Note representing the Series B 4.50% Convertible Senior Secured Notes due 2028, dated as of March 7, 2023, between Invitae Corporation and U.S. Bank Trust Company, National Association, as trustee.	8-K	4.3	3/8/2023	
4.5	Registration Rights Agreement, dated as of March 7, 2023, between Invitae Corporation and the investor party thereto.	8-K	10.1	3/8/2023	
10.1	Form of Purchase and Exchange Agreement.	8-K	10.1	3/1/2023	
10.2 [#]	Invitae Corporation 2015 Stock Incentive Plan, as amended and restated as of April 3, 2023.				X
31.1	Principal Executive Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Principal Financial Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1 [*]	Principal Executive Officer's Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).				X
32.2 [*]	Principal Financial Officer's Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).				X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase				X
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).				X

Indicates management contract or compensatory plan or arrangement.

- @ The schedules and exhibits to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request
- * In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INVITAE CORPORATION

By: _____
/s/ Kenneth D. Knight
Kenneth D. Knight
Chief Executive Officer
Principal Executive Officer

By: _____
/s/ Yafei (Roxi) Wen
Yafei (Roxi) Wen
Chief Financial Officer
Principal Financial Officer

Date: May 9, 2023

EXHIBIT 6

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): June 12, 2020

INVITAE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. Employer
Identification No.)

**1400 16th Street,
San Francisco, California**
(Address of principal executive offices)

94103
(Zip Code)

(415) 374-7782
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	The New York Stock Exchange LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(e)

On June 12, 2020, the Board of Directors (the “Board”) of Invitae Corporation (“Invitae”), including all of the independent members of the Board, approved, upon the recommendation of the Compensation Committee of the Board, a management incentive compensation plan for the 2020 fiscal year (the “Management Incentive Plan”). Under the Management Incentive Plan, Invitae’s executive officers, as well as other specified senior level employees, are participants in the Management Incentive Plan and may be eligible to receive incentive compensation in the form of performance restricted stock units (“RSUs”) based on the level of achievement of a specified 2020 cash burn goal. Eligibility to participate in the Management Incentive Plan and actual award amounts are not guaranteed and are determined at the discretion of the independent members of the Board upon the recommendation of the Compensation Committee of the Board. Potential payouts under the Management Incentive Plan may range from 0% to 100% of target RSU amounts and will be granted no later than March 31, 2021. RSUs awarded pursuant to the Management Incentive Plan vest as to 50% of the shares on the grant date, with the remaining 50% of the total amount of shares vesting on the first anniversary of the grant date, depending on eligibility and performance. Target RSU bonus amounts for Invitae’s named executive officers are as follows: Sean E. George—56,250 RSUs; Shelly D. Guyer—26,250 RSUs; Lee Bendekgey—26,250 RSUs; Robert L. Nussbaum—26,250 RSUs; and Katherine A. Stueland—26,250 RSUs.

In addition, the Board, including all of the independent members of the Board, approved, upon the recommendation of the Compensation Committee of the Board, grants of retention restricted stock units (“Retention RSUs”) and options to acquire shares of Invitae’s common stock (“Retention Options”) under the 2015 Stock Incentive Plan (the “2015 Plan”). The shares of common stock underlying Retention RSUs will vest in equal annual installments over a three year period, subject to continued service, with the first installment vesting on June 12, 2021. Retention Options vest over a four year period, subject to continued service, with 25% of the shares vesting on the first anniversary of the grant date, and the remaining 75% of each option award vesting monthly over the following three years. Each equity award is subject to the terms and conditions of the 2015 Plan and the applicable stock award agreements. Retention RSUs and Retention Options for Invitae’s named executive officers are as follows: Sean E. George—126,550 Retention RSUs and 42,200 Retention Options; Shelly D. Guyer—59,150 Retention RSUs and 19,600 Retention Options; Lee Bendekgey—59,150 Retention RSUs and 19,600 Retention Options; Robert L. Nussbaum—59,150 Retention RSUs and 19,600 Retention Options; and Katherine A. Stueland—59,150 Retention RSUs and 19,600 Retention Options.

On June 12, 2020, the Board approved an amendment and restatement of the 2015 Plan to provide for a modification in the method of calculating the pool of inducement shares and to increase the pool of inducement shares under the 2015 Plan by 475,000 shares of common stock, in accordance with New York Stock Exchange Rule 303A.08.

EXHIBIT 7

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
 WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report: June 26, 2020
(Date of earliest event reported)

Invitae Corporation

(Exact name of registrant as specified in its charter)

Delaware
 (State or other jurisdiction of
 incorporation or organization)

001-36847
 (Commission
 File Number)

27-1701898
 (I.R.S. employer
 identification number)

1400 16th Street, San Francisco, California 94103
 (Address of principal executive offices, including zip code)

(415) 374-7782
 (Registrant's telephone number, including area code)

N/A
 (Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	The New York Stock Exchange LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Effective June 29, 2020, Kenneth D. Knight will be appointed Chief Operating Officer of Invitae Corporation (“Invitae”). Upon his appointment, Invitae’s current Chief Operating Officer, Lee Bendekgey, will fully transition to lead Invitae’s payer relations, policy and government affairs, regulatory and QA compliance functions.

Mr. Knight, age 60, most recently served as Vice President of transportation services at Amazon.com, Inc., a multinational and diversified technology company, from December 2019 to June 2020, and as Vice President of Amazon’s global delivery and fulfillment human resources from April 2016 to December 2019. Prior to his time at Amazon, from 2012 to March 2016, Mr. Knight served as general manager of material handling and underground business division at Caterpillar Inc., a manufacturer of machinery and equipment. Prior to that, Mr. Knight served in various capacities at General Motors Company, a vehicle manufacturer, for 27 years, including as executive director of global manufacturing engineering and as manufacturing general manager. Mr. Knight holds a B.S. in Electrical Engineering from the Georgia Institute of Technology and a Master of Business Administration from the Massachusetts Institute of Technology.

In connection with Mr. Knight’s appointment as Chief Operating Officer, Invitae and Mr. Knight entered into an offer letter dated June 1, 2020 (the “Offer Letter”), pursuant to which Mr. Knight will be entitled to receive an annual base salary of \$500,000. Mr. Knight will be granted 250,000 restricted stock units (“RSUs”), which will vest in three equal annual installments on the anniversary of Mr. Knight’s start date. Within 30 days of his start date, Mr. Knight will be paid an additional \$500,000 as a sign-on bonus, which is to be repaid if he resigns before the anniversary of his start date. Mr. Knight will be granted an additional 75,000 RSUs which will vest with respect to 50% of the common stock underlying the RSUs six months after his start date, and with respect to the remainder, twelve months after his start date. All RSU grants will be subject to the terms and conditions of the 2015 Stock Incentive Plan and the applicable stock award agreements, and will be subject to a registration statement on Form S-8 covering the shares of common stock underlying the RSUs being filed with the Securities and Exchange Commission (the “SEC”). These RSU grants are intended to be inducement awards under Rule 303A.08 of the New York Stock Exchange. Mr. Knight will also be eligible to participate in Invitae’s management incentive compensation plan starting in the first quarter of 2021, in addition to medical and other employee benefits programs. Mr. Knight’s employment will be on an “at will” basis.

The foregoing summary of the Offer Letter is qualified in its entirety by reference to the Offer Letter, a copy of which is attached hereto as Exhibit 10.1 and incorporated herein by reference.

In connection with his appointment as Chief Operating Officer, Invitae expects to enter into its standard form of indemnification agreement with Mr. Knight. Mr. Knight has no family relationships with any of Invitae’s directors or executive officers, and he has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
10.1	Offer Letter, dated June 1, 2020, between Invitae Corporation and Kenneth D. Knight.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INVITAE CORPORATION

Date: June 26, 2020

By: /s/ Shelly D. Guyer
Name: Shelly D. Guyer
Title: Chief Financial Officer

EXHIBIT 8

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): April 30, 2021

INVITAE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. Employer
Identification No.)

**1400 16th Street,
San Francisco, California**
(Address of principal executive offices)

94103
(Zip Code)

(415) 374-7782
(Registrant's telephone number,
including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	The New York Stock Exchange LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

On May 4, 2021, Invitae Corporation (the “Company”) entered into a Sales Agreement (the “Agreement”) with Cowen and Company, LLC (the “Sales Agent”). The Agreement provides for the issuance and sale by the Company of common stock having an aggregate offering price of up to \$400,000,000. Pursuant to the Agreement, the Company may offer and sell the shares in transactions deemed to be an “at-the-market” offering as defined in Rule 415(a)(4) of the Securities Act of 1933, which shares can be sold by the Company from time to time, depending upon market demand, with the Sales Agent acting as an agent for sales.

The Company will pay the Sales Agent a commission of up to 3.0% of the gross proceeds from the sale of shares of common stock by it as agent under the Agreement. The Agreement provides that the Company will provide customary indemnification rights to the Sales Agent. The Company has no obligation to sell any shares of common stock pursuant to the Agreement and may at any time suspend sales pursuant to the Agreement. Either party may terminate the Agreement pursuant to the terms of the Agreement without liability of any party.

The shares of common stock will be sold pursuant to the Company’s automatic shelf registration statement on Form S-3 (File No. 333-230053), that was filed with the Securities and Exchange Commission and became automatically effective on March 4, 2019, including the related prospectus, dated March 4, 2019, as supplemented by the prospectus supplement dated May 4, 2021. This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state.

Under the Agreement, the Company may also sell shares of common stock to the Sales Agent as principal for its own account, at a price to be agreed upon at the time of sale. If the Company sells shares to the Sales Agent as principal, the Company will enter into a separate terms agreement with the Sales Agent, and the Company will describe the agreement in a separate prospectus supplement or pricing supplement.

The foregoing description of the Agreement does not purport to be complete and is subject to and qualified in its entirety by reference to the Agreement, a copy of which is attached hereto as Exhibit 1.1 and is incorporated herein by reference.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Management Incentive Compensation Plan

On April 30, 2021, upon the recommendation of the Compensation Committee (the “Compensation Committee”) of the Board of Directors of the Company (the “Board”), the Board (and with respect to that of Sean E. George, the Company’s Chief Executive Officer (the “CEO”), all of the independent members of the Board) approved a management incentive compensation plan for the 2021 fiscal year (the “Management Incentive Plan”). Under the Management Incentive Plan, the Company’s executive officers, as well as other specified senior level employees that are participants in the Management Incentive Plan, may be eligible to receive incentive compensation in the form of performance-based restricted stock units (“RSUs”) based on the level of achievement of specified 2021 performance goals directed at cash burn, revenue, SG&A as a percentage of revenue, and volume, except for Ms. Guyer who is transitioning to a new role leading the Company’s ESG efforts. Eligibility to participate in the Management Incentive Plan and actual award amounts are not guaranteed and are determined at the discretion of the independent members of the Board upon the recommendation of the Compensation Committee. Potential payouts under the Management Incentive Plan may be as low as 0% and may exceed 100% of target PRSU amounts based on relative achievement of the 2021 performance goals, and will be granted no later than March 31, 2022. PRSUs awarded pursuant to the Management Incentive Plan vest as to 50% of the shares on the grant date, with the remaining 50% of the total amount of shares vesting on the first anniversary of the grant date, depending on eligibility and performance. Target PRSU bonus amounts at 100% payout for the Company’s named executive officers and other executive officers are as follows: Sean E. George—59,700 PRSUs; Kenneth D. Knight—19,900 PRSUs; Katherine A. Stueland—19,900 PRSUs; Robert L. Nussbaum—19,900 PRSUs; Thomas R. Brida—19,900 PRSUs; and Lee Bendekgey—16,600 PRSUs.

Retention Equity Grants

On April 30, 2021, upon the recommendation of the Compensation Committee, the Board (and with respect to that of the CEO, all of the independent members of the Board) approved grants of retention restricted stock units (“Retention RSUs”) and options to acquire shares of the Company’s common stock (“Retention Options”) under the 2015 Stock Incentive Plan (the “2015 Plan”) to the Company’s executive officers, as well as other specified senior level employees, except for Ms. Guyer who is transitioning to a new role leading the Company’s ESG efforts. The shares of common stock underlying Retention RSUs will vest in equal annual installments over a three year period, subject to continued service, with the first installment vesting on May 15, 2022. Retention Options vest over a four year period, subject to continued service, with 25% of the shares vesting on the first anniversary of the grant date, and the remaining 75% of each option award vesting monthly over the following three years. Each equity award is subject to the terms and conditions of the 2015 Plan and the applicable stock award agreements. Retention RSUs and Retention Options for the Company’s named executive officers and other executive officers are as follows: Sean E. George—134,200 Retention RSUs and 69,500 Retention Options; Kenneth D. Knight—44,700 Retention RSUs and 23,200 Retention Options; Katherine A. Stueland—44,700 Retention RSUs and 23,200 Retention Options; Robert L. Nussbaum—44,700 Retention RSUs and 23,200 Retention Options; Thomas R. Brida—44,700 Retention RSUs and 23,200 Retention Options; and Lee Bendekgey—37,300 Retention RSUs and 19,300 Retention Options.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
--------------------	--------------------

- 1.1 [Sales Agreement dated May 4, 2021 between Invitae Corporation and Cowen and Company, LLC.](#)
- 5.1 [Opinion of Pillsbury Winthrop Shaw Pittman LLP.](#)
- 23.1 [Consent of Pillsbury Winthrop Shaw Pittman LLP \(included in Exhibit 5.1\).](#)
- 104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 4, 2021

INVITAE CORPORATION

By: /s/ Shelly D. Guyer

Name: Shelly D. Guyer

Title: Chief Financial Officer

EXHIBIT 9

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): April 9, 2022

INVITAE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. Employer
Identification No.)

**1400 16th Street,
San Francisco, California**
(Address of principal executive offices)

94103
(Zip Code)

(415) 374-7782
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	The New York Stock Exchange LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Management Incentive Compensation Plan

On April 9, 2022, upon the recommendation of the Compensation Committee (the “Compensation Committee”) of the Board of Directors of the Company (the “Board”), the Board (and with respect to that of Sean E. George, the Company’s Chief Executive Officer (the “CEO”), all of the independent members of the Board) approved a management incentive compensation plan for the 2022 fiscal year (the “Management Incentive Plan”). Under the Management Incentive Plan, the Company’s executive officers, as well as other specified senior level employees that are participants in the Management Incentive Plan, may be eligible to receive incentive compensation in the form of cash payments based on the level of achievement of specified 2022 performance goals related to cash burn, revenue, and gross margin. Eligibility to participate in the Management Incentive Plan and actual award amounts are not guaranteed and are determined at the discretion of the independent members of the Board or the Compensation Committee. The Board retains sole discretion to modify, change, or terminate the Management Incentive Plan, and with the approval of the independent members of the Board or the Compensation Committee, has full discretion to modify the payout amounts. Potential payouts under the Management Incentive Plan may be as low as 0% and may exceed 100% of target cash amounts based on relative achievement of the 2022 performance goals, and will be determined no later than March 15, 2023. 50% of the payouts awarded pursuant to the Management Incentive Plan will be paid following the determination date, with the remaining 50% paid on the first anniversary of the determination date, subject to continued service. Target cash bonus amounts at 100% payout for the Company’s executive officers are as follows: Sean E. George—\$1,500,000; Roxi (Yafei) Wen—\$600,000; Thomas R. Brida—\$500,000; Kenneth D. Knight—\$600,000; and Robert L. Nussbaum—\$500,000.

Retention Equity Grants

On April 9, 2022, upon the recommendation of the Compensation Committee, the Board (and with respect to that of the CEO, all of the independent members of the Board) approved grants of retention restricted stock units (“Retention RSUs”) under the 2015 Stock Incentive Plan (the “2015 Plan”) to the Company’s executive officers, as well as other specified senior level employees. The shares of common stock underlying Retention RSUs will vest in equal annual installments over a three-year period, subject to continued service, with the first installment vesting on May 15, 2023. Each equity award is subject to the terms and conditions of the 2015 Plan and the applicable stock award agreements. Retention RSUs for the Company’s executive officers are as follows: Sean E. George—0 Retention RSUs; Roxi (Yafei) Wen—225,000 Retention RSUs; Thomas R. Brida—168,511 Retention RSUs; Kenneth D. Knight—225,000 Retention RSUs; and Robert L. Nussbaum—168,511 Retention RSUs.

EXHIBIT 10

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): July 16, 2022

Invitae Corporation
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. Employer
Identification No.)

**1400 16th Street,
San Francisco, California**
(Address of principal executive offices)

94103
(Zip Code)

(415) 374-7782
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	The New York Stock Exchange LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On July 18, 2022, Invitae Corporation (the “Company”) issued a press release announcing certain preliminary financial results for its fiscal quarter ended June 30, 2022 (the “Press Release”). The full text of the Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On July 18, 2022, the Company announced plans to strategically realign its operations and implement cost reduction programs to prioritize its core genome sequencing and genome management platforms, which realignment plan was approved by the Board of Directors of the Company on July 16, 2022. The Company plans to streamline its product portfolio to focus on its core testing business and programs that drive near-term cost of goods sold reductions, with the goals of accelerating the company’s path to positive operating cash flow and completing its genome management platform. The realignment plan will result in a reduction of more than 1,000 employees. As part of the realignment plan, the Company intends to streamline its international operations by focusing its international operations to fewer than a dozen countries and exiting certain territories and countries where the Company’s business is less developed. The realignment plan is expected to result in approximately \$326 million in annualized cash savings, which is expected to be fully realized by 2023. The Company currently expects that the realignment plan will be completed by June 30, 2023. The Company currently estimates it will incur cash charges of approximately \$75-100 million related to the realignment plan, in addition to non-cash charges which it is currently not able to estimate.

Item 7.01 Regulation FD Disclosure.

On July 18, 2022, the Company used an investor presentation on a conference call with investors. The investor presentation and the script of the conference call are furnished as Exhibits 99.2 and 99.3, respectively, to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.2 and 99.3, shall not be deemed to be filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the expected impact, benefits, costs, parameters, details and timing of the company’s strategic business realignment plan or various aspects thereof; the company’s future financial and operating results, including estimated annual cost savings and the expected timing or realization thereof; the company’s expectations regarding future operating cash flows; and the company’s expectations regarding its genome management platform and the benefits thereof. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the ability of the company to successfully execute its strategic business realignment plan and achieve the intended benefits thereof on the expected timeframe or at all; unforeseen or greater than expected costs associated with the realignment plan; the risk that the disruption that may result from the realignment may harm the company’s business, market share or its relationship with customers or potential customers; and the other risks set forth in the company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. These forward-looking statements speak only as of the date hereof, and the Company disclaims any obligation to update these forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Invitae Corporation dated July 18, 2022.
99.2	Investor Presentation dated July 18, 2022.
99.3	Script of July 18, 2022, Conference Call.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 18, 2022

INVITAE CORPORATION

By: /s/ Thomas R. Brida

Name: Thomas R. Brida

Title: General Counsel

EXHIBIT 11

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): August 22, 2022

INVITAE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. Employer
Identification No.)

**1400 16th Street,
San Francisco, California**
(Address of principal executive offices)

94103
(Zip Code)

(415) 374-7782
(Registrant's telephone number,
including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	The New York Stock Exchange LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**Retention Awards**

On August 22, 2022, upon the recommendation of the Compensation Committee of the Board of Directors (the “**Board**”) of Invitae Corporation (the “**Company**”), the Board approved grants of retention restricted stock units (“**Retention RSUs**”) under the Company’s 2015 Stock Incentive Plan (the “**2015 Plan**”) to certain of the Company’s executive officers. The Retention RSUs will vest 100% on August 15, 2023, assuming the applicable recipient’s continuous service as a full-time employee of the Company through such date. Each grant of Retention RSUs is subject to the terms and conditions of the 2015 Plan and the applicable award agreement. Retention RSUs for the Company’s executive officers are as follows: Roxi (Yafei) Wen – 102,000 Retention RSUs; Thomas R. Brida – 54,000 Retention RSUs; Robert L. Nussbaum – 54,000 Retention RSUs; and Robert F. Werner – 54,000 Retention RSUs.

EXHIBIT 12



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February 28, 2023

Invitae Announces Convertible Notes and Share Exchange and New Convertible Notes Issuance

- In a transaction led by Deerfield Management, the Company effectively addresses ~96% of its 2024 convertible debt obligations -
- Participating holders to exchange 90% of their existing 2024 notes for new notes due in 2028 and equitize 10% of their holdings; Certain investors will also provide an additional \$30 million of capital -
- The Company will discuss this announcement during its fourth quarter and full year 2022 earnings call at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time -

SAN FRANCISCO, Feb. 28, 2023 /PRNewswire/ -- [Invitae](#) (NYSE: NVTA), a leading medical genetics company, today announced that it has signed exchange and financing agreements with a fund managed by Deerfield Management Company and other investors (collectively, the "Investors").



The privately negotiated agreements with the Investors' holdings of the Company's outstanding 2.00% Convertible Senior Notes due 2024 (the "Old Notes") calls for the exchange of approximately \$306 million aggregate principal amount of the Old Notes into approximately \$275 million aggregate principal amount of new 4.50% Series A Convertible Senior Secured Notes due 2028 (the "New Notes"), along with approximately 14.3 million shares of the Company's common stock

(the "Shares"). Invitae will also sell \$30 million of New Notes to the Investors for cash. These transactions are subject to customary closing conditions and are expected to close on or about March 7, 2023. The New Notes will be issued pursuant to an indenture.

"We are extremely pleased to have accomplished several important objectives for the Company and its stockholders with this transaction," said Ken Knight, president and chief executive officer of Invitae. "We have added \$30 million in cash to our balance sheet and successfully refinanced the vast majority of our short-term obligations through 2028. With this demonstrated commitment from long-term financial investors, Invitae can focus on its goal of achieving positive cash flow and deliver on its mission to bring comprehensive genetic information into mainstream medicine to improve healthcare for billions of people."

Based on the initial conversion price of \$2.5740, the New Notes will be convertible into approximately 118.6 million shares of Common Stock, subject to the potential issuance of additional shares in certain events. Subject to certain requirements under the indenture, the Company will have the option to redeem all or any portion of the principal amount of the New Notes for cash and the issuance of warrants. The New Notes will be convertible at any time at the option of the holders thereof, subject to beneficial ownership cap and/or certain limitations imposed by the NYSE rules (if applicable) for any conversion into shares of Common Stock. The New Notes will be secured by a security interest in substantially all of the assets of the Company and its material subsidiaries and a pledge of the equity interests of the Company's direct and indirect subsidiaries.

"We are encouraged by the disciplined approach that Invitae has taken toward improving its operating metrics and balance sheet while continuing to invest to achieve its ambition to be a leader in applied genetics," said Avi Kometz, M.D., partner at Deerfield Management. "We view this financing as an important step in giving the Company the flexibility and runway to reach its goals."

The New Notes, the Shares and any shares of common stock issuable upon conversion of the New Notes have not been registered under the Securities Act of 1933, as amended, or under any state securities laws and may not be offered or sold without registration under, or an applicable exemption from, the registration requirements; provided that the New Notes (and underlying conversion shares) and Shares issued in exchange for the Old Notes will be freely tradeable by holders that are not affiliates of Invitae pursuant to Rule 144 under the Securities Act.

J. Wood Capital Advisors LLC, Goldman Sachs & Co. LLC, and Perella Weinberg Partners LP acted as financial advisors on the transaction. Latham & Watkins LLP acted as legal counsel to the Company in connection with the Transaction, Katten Muchin Rosenman LLP acted as legal counsel to Deerfield Management in connection with the Transaction, and Cooley LLP acted as legal counsel to the financial advisors in connection with the Transaction.

This press release does not constitute an offer to sell or a solicitation of an offer to buy, nor shall there be any sale of these securities in any

OTC: NVTA

\$0.01

+0.01 +900.00%

Volume: 284,226

20 minute delay

INVESTOR TOOLKIT

- [Invitae's Third Quarter 2023 Financial Results Conference Call](#)
- [Invitae Reports Third Quarter 20: Financial Results](#)
- [Third Quarter 2023 Financial Res Conference Call Earnings Presentation](#)
- [8-K](#)

FEATURE PRESENTATION



Bringing genetic information into mainstream medical practice.

[VIEW](#)

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- SEC Filing
- Presentation
- Event
- End of Day Stock Quote



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Management will discuss this announcement during its fourth quarter and full year 2022 earnings results call today at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time. To access the conference call, please register at the link below:

<https://www.netroadshow.com/events/login?show=d75171b5&confid=46549>

Upon registering, each participant will be provided with call details and access codes.

The live webcast of the call and slide deck may be accessed [here](#) or by visiting the investors section of the Company's website at ir.invitae.com. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the Company's website.

About Invitae

Invitae (NYSE: NVTA) is a leading medical genetics company trusted by millions of patients and their providers to deliver timely genetic information using digital technology. We aim to provide accurate and actionable answers to strengthen medical decision-making for individuals and their families. Invitae's genetics experts apply a rigorous approach to data and research, serving as the foundation of their mission to bring comprehensive genetic information into mainstream medicine to improve healthcare for billions of people.

To learn more, visit invitae.com and follow for updates on [Twitter](#), [Instagram](#), [Facebook](#) and [LinkedIn](#) @Invitae.

Safe Harbor Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the closing of the transaction, including the timing of and conditions to closing; the anticipated use of proceeds from the transaction; and any expected benefits from the transaction. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: risks related to whether the Company will be able to satisfy the conditions required to close the transaction; the fact that the Company's management will have broad discretion in the use of the proceeds from the transaction and risks and uncertainties related that use of proceeds; the potential impact of market and other general economic conditions; the ability of the Company to successfully execute its strategic business realignment plan and achieve the intended benefits thereof on the expected timeframe or at all; the Company's failure to manage growth effectively; the Company's failure to fully realize the anticipated benefits of the transaction; and the other risks set forth in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 and in the Company's subsequent filings with the Commission. These forward-looking statements speak only as of the date hereof, and the Company disclaims any obligation to update these forward-looking statements.

Contacts for Invitae:

Investor Relations

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Public Relations

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pr@invitae.com

View original content to download multimedia:<https://www.prnewswire.com/news-releases/invitae-announces-convertible-notes-and-share-exchange-and-new-convertible-notes-issuance-301758676.html>

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INVESTOR CONTACT

1400 16th St.
San Francisco, CA, 94103



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EXHIBIT 13

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): April 3, 2023

INVITAE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. Employer
Identification No.)

**1400 16th Street,
San Francisco, California**
(Address of principal executive offices)

94103
(Zip Code)

(415) 374-7782
(Registrant's telephone number,
including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	The New York Stock Exchange LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to be extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 1333 of the Exchange Act.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**Management Incentive Compensation Plan**

On April 3, 2023, upon the recommendation of the Compensation Committee (the “Compensation Committee”) of the Board of Directors of the Company (the “Board”), the Board (and with respect to that of Kenneth D. Knight, the Company’s Chief Executive Officer (the “CEO”), all of the independent members of the Board) approved a management incentive compensation plan for the 2023 fiscal year (the “Management Incentive Plan”). Under the Management Incentive Plan, the Company’s executive officers, as well as other specified senior level employees that are participants in the Management Incentive Plan, may be eligible to receive incentive compensation in the form of cash payments based on the level of achievement of specified 2023 performance goals related to cash burn, revenue, and gross margin. Eligibility to participate in the Management Incentive Plan and actual award amounts are not guaranteed and are determined at the discretion of the independent members of the Board or the Compensation Committee. The Board retains sole discretion to modify, change, or terminate the Management Incentive Plan, and with the approval of the independent members of the Board or the Compensation Committee, has full discretion to modify the payout amounts. Potential payouts under the Management Incentive Plan may be as low as 0% and may exceed 100% of target cash amounts based on relative achievement of the 2023 performance goals, and will be determined no later than March 15, 2024. 100% of the payouts awarded pursuant to the Management Incentive Plan will be paid following the determination date, subject to continued service. Target cash bonus amounts at 100% payout for the Company’s executive officers are as follows: Kenneth D. Knight—\$1,125,000; Roxi (Yafei) Wen—\$500,000; Thomas R. Brida—\$275,400; and Robert L. Nussbaum—\$270,000.

Executive Management Salaries

On April 3, 2023, upon the recommendation of the Compensation Committee, the Board approved increases in base salaries for certain of the Company’s executive officers as well as a specified senior level employee. Resulting base salaries for the affected Company’s executive officers are as follows: Roxi (Yafei) Wen—\$500,000 (increase of \$25,000); Thomas R. Brida—\$459,000 (increase of \$34,000); and Robert L. Nussbaum—\$450,000 (increase of \$50,000).

Retention Equity Grants and Cash Payments

On April 3, 2023, upon the recommendation of the Compensation Committee, the Board (and with respect to that of the CEO, all of the independent members of the Board) approved (i) grants of retention restricted stock units (“Retention RSUs”) under the Company’s 2015 Stock Incentive Plan (the “2015 Plan”) to the Company’s executive officers as well as other specified senior level employees and (ii) cash retention payments (“Retention Payments”) to certain of the Company’s executive officers as well as other specified senior level employees. The shares of common stock underlying Retention RSUs will vest in equal annual installments over a three-year period, subject to continued service, with the first installment vesting on May 15, 2024. Each equity award is subject to the terms and conditions of the 2015 Plan and the applicable stock award agreements. Retention RSUs for the Company’s executive officers are as follows: Kenneth D. Knight—1,200,000 Retention RSUs; Roxi (Yafei) Wen—300,000 Retention RSUs; Thomas R. Brida—300,000 Retention RSUs; and Robert L. Nussbaum—155,000 Retention RSUs. The Retention Payments will be paid in equal annual installments over a three-year period, subject to continued service, with the first installment paid on May 15, 2024. The aggregate amount of the Retention Payments for certain of the Company’s executive officers are as follows: Kenneth D. Knight—\$1,000,000; Roxi (Yafei) Wen—\$500,000; and Thomas R. Brida—\$400,000.

Retention Bonuses

On April 3, 2023, upon the recommendation of the Compensation Committee, the Board (and with respect to that of the CEO, all of the independent members of the Board) approved cash retention bonuses for the 2023 fiscal year for the Company’s executive officers, as well as other specified senior level employees. 50% of the retention bonuses will be paid at the end of June 2023, with the remaining 50% paid at the end of December 2023, subject to continued service. The aggregate amount of the retention bonuses for the Company’s executive officers are as follows: Kenneth D. Knight—\$500,000; Roxi (Yafei) Wen—\$250,000; Thomas R. Brida—\$80,000; and Robert L. Nussbaum—\$80,000.

EXHIBIT 14

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 13, 2023



Invitae Corporation

(Exact name of the registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. employer
identification number)

1400 16th Street, San Francisco, California 94103
(Address of principal executive offices, including zip code)

(415) 374-7782
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Management Retention Arrangements

On October 18, 2023, upon the recommendation of the Compensation Committee of the Board of Directors (the “Board”) of Invitae Corporation (the “Company”), the Board (and all of the independent members of the Board) approved certain management retention arrangements for certain officers of the Company as follows:

- Kenneth D. Knight (Chief Executive Officer and President). Subject to a repayment obligation that will lapse over a two-year period, the Company agreed to pay Mr. Knight a one-time cash retention bonus of \$3,500,000, subject to applicable withholding and deductions. This bonus will be earned and vest in eight equal quarterly installments over two years beginning with the first installment on the date three months after October 19, 2023, subject to Mr. Knight’s continued employment with the Company on the applicable quarterly vesting date. If Mr. Knight’s employment with the Company terminates for any reason other than as a result of an involuntary termination (e.g., a termination without cause or as a result of a material reduction in authority, a material reduction in base compensation or a relocation by more than 50 miles of principal place of employment) prior to October 19, 2025, Mr. Knight will be required to repay any portion of such bonus that is unearned and unvested on the termination date. The Board also unilaterally terminated Mr. Knight’s participation in a 2023 long-term cash retention program approved by the Board on April 3, 2023, pursuant to which Mr. Knight would otherwise have been eligible for up to \$1,000,000 in total payments, paid in equal annual installments over a three-year period subject to continued service, with the first installment to have been paid on May 15, 2024. The foregoing description of the cash retention bonus for Mr. Knight is qualified in its entirety by reference to the Long-Term Retention Bonus Agreement between the Company and Mr. Knight, a copy of which is attached hereto as Exhibit 10.1 and incorporated herein by reference.
- Thomas R. Brida (General Counsel, Chief Compliance Officer and Secretary). If Mr. Brida (i) remains actively employed by the Company in his current position through December 15, 2023, unless Mr. Brida is offered and accepts a different role or position with the Company or is terminated not for “cause” (as defined in the Company’s form of Change of Control and Severance Agreement for certain officers of the Company, a copy of which is attached hereto as Exhibit 10.2 and incorporated herein by reference – the “COC Agreement”) prior to December 15, 2023, and (ii) performs his duties for the Company, including specific projects assigned to him, and otherwise complies with his continuing obligations to the Company, then Mr. Brida will receive a payment of \$100,000, subject to applicable withholding and deductions. If Mr. Brida performs his duties, including specific projects assigned to him, and otherwise complies with his continuing obligations to the Company and remains actively employed by the Company in his current position through: (i) March 15, 2024, then Mr. Brida will receive a payment of \$114,750, subject to applicable withholding and deductions; (ii) August 15, 2024, then Mr. Brida will receive a grant of restricted stock units (“RSUs”) under the Company’s 2015 Stock Incentive Plan (the “2015 Plan”) covering 229,500 shares of the Company’s common stock, with such grant fully vested when made and subject to the terms and conditions of the 2015 Plan and the applicable stock award agreement; and (iii) August 16, 2024, then Mr. Brida will receive a payment of \$114,750, subject to applicable withholding and deductions. The foregoing description of retention cash payments and a retention RSU grant for Mr. Brida is qualified in its entirety by reference to the Retention & Bonus Agreement between the Company and Mr. Brida, a copy of which is attached hereto as Exhibit 10.3 and incorporated herein by reference. In addition to the foregoing, the term of Mr. Brida’s existing COC Agreement, which otherwise would have expired on April 23, 2024, is extended until October 18, 2026.

Appointment of David B. Sholehvar, MD as Chief Operating Officer

On October 18, 2023, the Board appointed David B. Sholehvar, MD as Chief Operating Officer of the Company, effective November 13, 2023.

David B. Sholehvar, MD, 56, served as President, Clinical Services Division, of NeoGenomics, Inc. (Nasdaq: NEO), an oncology diagnostics company, from March 2022 to November 2022. Prior to that, from April 2017 to October 2020, Dr. Sholehvar served as Chief Executive Officer for Dynex Technologies, Inc., a manufacturer of laboratory instruments and technology. Dr. Sholehvar served in various capacities at Quest Diagnostics, a provider of diagnostic information services, including as Vice President from 2014 to 2017 and General Manager from 2013 to 2014. Dr. Sholehvar also served in various capacities at Ortho Clinical Diagnostics, Inc., a former Johnson & Johnson company and provider of in vitro diagnostics, including as Vice President, Americas and EMEA from 2012 to 2013, Vice President, Clinical Innovations and Franchise Board Member from 2010 to 2011, and General Manager from 2007 to 2009. From 2011 to 2012, Dr. Sholehvar served as General Manager and Franchise Board Member of Cellular Technologies, Inc., a former Johnson & Johnson company and provider of medical devices and molecular diagnostics. Dr. Sholehvar holds a BS from the University of Pittsburgh, an MD from Thomas Jefferson University, and an MBA from the Joseph M. Katz Graduate School of Business at the University of Pittsburgh.

In connection with Dr. Sholehvar's appointment as Chief Operating Officer, Dr. Sholehvar and the Company entered into an offer letter (the "Offer Letter"), pursuant to which Dr. Sholehvar will be entitled to receive an annual base salary of \$460,000. Dr. Sholehvar will be granted 850,000 RSUs, which will vest over a three-year period, subject to Dr. Sholehvar's continued service with the Company through the applicable vesting dates. Dr. Sholehvar's RSU grants will be subject to the terms and conditions of the 2015 Plan and the applicable stock award agreements. Dr. Sholehvar will be paid \$150,000 as a sign-on bonus, which is to be repaid if he resigns before the anniversary of his start date. In addition, Dr. Sholehvar will be eligible for a retention bonus of \$150,000 that will become payable on May 13, 2024 (and thereafter be subject to a claw-back that lapses, based upon continuing service, in equal monthly amounts over a 12-month period). Dr. Sholehvar will also be eligible to participate in the Company's management incentive compensation plan and the Company's medical and other employee benefits programs. Dr. Sholehvar's employment will be on an "at will" basis.

The foregoing summary is qualified in its entirety by reference to the Offer Letter and the Retention Bonus Agreement, copies of which are attached hereto as Exhibit 10.4 and Exhibit 10.5, respectively, and incorporated herein by reference.

In connection with his appointment as Chief Operating Officer, the Company expects to enter into its form of COC Agreement and form of indemnification agreement with Dr. Sholehvar. There is no arrangement or understanding between Dr. Sholehvar and any other person pursuant to which he was selected as an officer of the Company. Additionally, there are no family relationships between any director or executive officer of the Company and Dr. Sholehvar, and Dr. Sholehvar has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1#	Long-Term Retention Bonus Agreement, dated as of October 19, 2023, by and between Invitae Corporation and Kenneth D. Knight.
10.2#	Form of Change of Control and Severance Agreement between Invitae Corporation and certain officers of Invitae Corporation (incorporated by reference to Exhibit 10.6 of Invitae Corporation's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2021).
10.3#*	Retention & Bonus Agreement, dated as of October 19, 2023, by and between Invitae Corporation and Thomas R. Brida.
10.4#	Offer Letter, effective as of November 13, 2023, by and between Invitae Corporation and David B. Sholehvar.
10.5#	Retention Bonus Agreement, dated as of October 13, 2023, by and between Invitae Corporation and David B. Sholehvar.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Indicates management contract or compensatory plan or arrangement.

* Portions of this exhibit have been redacted in accordance with Item 601(b)(10)(iv) of Regulation S-K. An unredacted copy of this exhibit will be provided to the Securities and Exchange Commission upon request.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: October 19, 2023

INVITAE CORPORATION

By: /s/ Ana J. Schrank
Name: Ana J. Schrank
Title: Chief Financial Officer

INVITAE CORPORATION
LONG-TERM RETENTION BONUS AGREEMENT

This Long-Term Retention Bonus Agreement (this “Agreement”) is made and entered into effective as of October 19, 2023 (the “Effective Date”), by and between Kenneth D. Knight (“Executive”) and Invitae Corporation, a Delaware corporation (the “Company”). Certain capitalized terms used in this Agreement are defined in Section 1 below.

The Board of Directors of the Company (the “Board”) recognizes Executive’s contributions to the Company and, to encourage and incentivize Executive to remain employed by the Company, the Board believes that it is in the best interests of the Company and its stockholders to provide Executive with a long-term retention bonus pursuant to the terms set forth in this Agreement.

AGREEMENT

In consideration of the mutual covenants herein contained and the continued employment of Executive by the Company, the parties agree as follows:

1. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) Cause. “Cause” shall mean Executive’s (i) commission of a felony, an act involving moral turpitude, or an act constituting common law fraud, and which has an adverse effect on the business or affairs of the Company or its affiliates or stockholders; (ii) intentional or willful misconduct or refusal to follow the lawful instructions of the Board that is not cured within thirty (30) days following written notice from the Board; (iii) commission of any violation of a Company policy that has a material adverse effect on the business or reputation of the Company; or (iv) intentional breach of Company confidential information obligations which has an adverse effect on the Company or its affiliates or stockholders. For these purposes, no act or failure to act shall be considered “intentional or willful” unless it is done, or omitted to be done, in bad faith without a reasonable belief that the action or omission is in the best interests of the Company.

(b) Involuntary Termination. “Involuntary Termination” shall mean:

(i) a material reduction in Executive’s title, duties, authorities or responsibilities as the Chief Executive Officer of the Company without the Executive’s consent;

(ii) without Executive’s express written consent, a reduction by the Company of Executive’s base compensation of more than ten percent (10%), unless such reduction in base compensation is part of a general reduction in compensation applicable to senior executives of the Company;

(iii) without Executive’s express written consent, the relocation of Executive’s principal place of employment to a facility or a location more than fifty (50) miles from its location as of the Effective Date;

(iv) any termination of Executive’s employment by the Company which is not effected for Cause;

or

(v) the failure of the Company to obtain the assumption of this Agreement or any other agreement between the Company and Executive by any successors contemplated in Section 8 below.

A termination shall not be considered an “Involuntary Termination” unless Executive provides notice to the Company of the existence of the condition described in subsections (i), (ii), (iii), (iv) or (v) above within ninety (90) days of the initial existence of such condition, the Company fails to remedy the condition within thirty (30) days following the receipt of such notice, and Executive terminates employment within one-hundred eighty (180) days following the initial existence of such condition. A termination due to death or disability shall not be considered an Involuntary Termination.

(c) Termination Date. “Termination Date” shall mean Executive’s “separation from service” within the meaning of that term under Section 409A of the Internal Revenue Code of 1986, as amended (the “Code”).

2. Long-Term Retention Bonus. Subject to the Repayment Obligation set forth in Section 3, the Company will pay Executive a one-time cash retention bonus of Three Million Five Hundred Thousand Dollars (\$3,500,000) (the “Long-Term Retention Bonus”), subject all to applicable withholdings and deductions required by law or pursuant to Company policy. The Long-Term Retention Bonus will be paid to Executive not later than ten (10) business days following the Effective Date.

3. Vesting and Repayment. The Long-Term Retention Bonus will be earned and vest in eight (8) equal quarterly installments over two (2) years beginning on the three (3)-month anniversary of the Effective Date, subject to Executive’s continued employment with the Company on the applicable quarterly vesting date. In the event that Executive’s employment with the Company terminates for any reason other than as a result of an Involuntary Termination prior to the second anniversary of the Effective Date, Executive will be required to repay, and hereby agrees to repay, to the Company (or a designated affiliate) any portion of the Long-Term Retention Bonus that is unearned and unvested on the Termination Date (with such repayment amount determined based on the Long-Term Retention Bonus before reduction for applicable withholdings and deductions) (the “Repayment Obligation”). Subject to Executive’s continued employment with the Company, the Repayment Obligation shall terminate with respect to 12.5% of the Long-Term Retention Bonus on each three (3)-month anniversary of the Effective Date.

4. Discretion. The Board (or a designated committee thereof) is responsible for the general administration of the Long-Term Retention Bonus and shall have all powers and duties necessary to fulfill these responsibilities, including, but not limited to, the full discretionary authority to interpret, administer and apply the terms of this Agreement, including the Repayment Obligation. The validity of any such interpretation, construction, decision, or finding of fact shall not be given de novo review if challenged in court, by arbitration, or in any other forum, and shall be upheld unless clearly arbitrary or capricious.

5. At-Will Employment. The Company and Executive acknowledge that Executive’s employment is and shall continue to be at-will, as defined under applicable law. The Company reserves the right to terminate Employee’s employment at any time with or without cause or prior notice.

6. Limitation on Payments. In the event that the benefits provided for in this Agreement or otherwise payable to Executive (i) constitute “parachute payments” within the meaning of Section 280G of the Code and (ii) would be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then Executive’s benefits under this Agreement shall be either:

(a) delivered in full or

(b) delivered as to such lesser extent which would result in no portion of such benefits being subject to the Excise Tax,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Executive on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code.

Unless the Company and Executive otherwise agree in writing, any determination required under this Section 6 shall be made in writing by the Company's independent public accountants (the "Accountants"), whose determination shall be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required by this Section 6, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section 6. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 6. In the event that a reduction is required, the reduction shall be applied first to any benefits that are not subject to Section 409A of the Code, and then shall be applied to benefits (if any) that are subject to Section 409A of the Code, with the benefits payable latest in time subject to reduction first.

7. Section 409A; Delayed Commencement of Benefits. The parties intend that any amounts payable hereunder comply with or are exempt from Section 409A of the Code ("Section 409A"), and this Agreement shall be administered accordingly. In the event that any changes to this Agreement or any additional terms are required to ensure that a payment is either exempt from or complies with Section 409A so that the penalty taxes under Section 409A(a)(1)(B) are not applied, Executive hereby agrees that the Company may make such change or incorporate such terms (by reference or otherwise) without Executive's consent. Each payment contemplated by this Agreement will be treated as a separate payment for purposes of Section 409A. Notwithstanding anything herein to the contrary, the Company shall have no liability to the Executive or to any other person if the payments and benefits provided in this Agreement that are intended to be exempt from or compliant with Section 409A are not so exempt or compliant, as applicable.

8. Successors.

(a) Company's Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the Company's rights and obligations under this Agreement and agree expressly to perform the Company's obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which executes and delivers the assumption agreement described in this subsection (a) or which becomes bound by the terms of this Agreement by operation of law.

(b) Executive's Successors. Without the written consent of the Company, Executive shall not assign or transfer this Agreement or any right or obligation under this Agreement to any other person or entity. Notwithstanding the foregoing, the terms of this Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable

by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

9. Notices.

(a) General. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of Executive, mailed notices shall be addressed to Executive at the home address which he most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(b) Notice of Termination. Any termination by the Company for Cause or by Executive as a result of an Involuntary Termination shall be communicated by a notice of termination to the other party hereto given in accordance with this Section 9. Such notice shall indicate the specific termination provision in this Agreement relied upon, shall set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and shall specify the Termination Date (which shall be not more than thirty (30) days after the giving of such notice). The failure by Executive to include in the notice any fact or circumstance which contributes to a showing of Involuntary Termination shall not waive any right of Executive hereunder or preclude Executive from asserting such fact or circumstance in enforcing Executive's rights hereunder, subject to the requirements of Section 1(b).

10. Arbitration. Any controversy involving the construction or application of any terms, covenants or conditions of this Agreement, or any claims arising out of any alleged breach of this Agreement, will be governed by the rules of the American Arbitration Association and submitted to and settled by final and binding arbitration in San Francisco, California, except that any alleged breach of Executive's confidential information obligations shall not be submitted to arbitration and instead the Company may seek all legal and equitable remedies, including without limitation, injunctive relief.

11. Miscellaneous Provisions.

(a) Waiver. No provision of this Agreement may be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(b) Integration. The Board (or a designated committee thereof) has or is expected to unilaterally terminate Executive's participation in the 2023 long-term cash retention program approved by the Board on April 3, 2023. This Agreement supersedes and replaces any prior agreements, representation or understandings, whether written, oral, express or implied, between Executive and the Company, including any unearned 2023 long-term cash retention program benefit(s), and constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof.

(c) Unfunded Arrangement. No provision of this Agreement shall require the Company to segregate any assets for the purpose of satisfying any obligations under this Agreement, nor shall Executive or other person have any interest in any particular assets of the

Company by reason of the right to receive the Long-Term Retention Bonus under this Agreement.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(f) Employment Taxes. The Long-Term Retention Bonus shall be subject to withholding of applicable income and employment taxes when paid. In the event that Executive repays all or a portion of the Long-Term Retention Bonus to the Company (or its designated affiliate) pursuant to the Repayment Obligation, Executive acknowledges that Executive may not be able to recover taxes previously withheld or paid on Executive's receipt of the Long-Term Retention Bonus. Executive hereby acknowledges and agrees that the Company shall have no liability to Executive or to any other person with respect to the recovery of any taxes previously paid or payable by or on behalf of Executive in respect of the payment of the Long-Term Retention Bonus in the event that any portion of the Long-Term Retention Bonus is repaid by Executive to the Company (or its designated affiliate) pursuant to the Repayment Obligation.

(g) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY: INVITAE CORPORATION
By: /s/ Thomas R. Brida
Name: Thomas R. Brida
Title: General Counsel

EXECUTIVE: /s/ Kenneth D. Knight
Signature
Printed Name: Kenneth D. Knight
Title: Chief Executive Officer

Exhibit 10.3

[**] Indicates that certain information in this exhibit has been excluded because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

RETENTION & [] BONUS AGREEMENT**

This Retention & [**] Bonus Agreement (“Agreement”) is made and entered into as of the date of execution by all parties as indicated below, by and between **Invitae Corporation** (the “Company”) and **Tom Brida** (“Employee”) with respect to the following facts:

- A. Employee is currently employed by the Company.
- B. [**].
- C. The Company recognizes and values Employee’s contributions to the Company [**]. Accordingly, the Company enters into this Agreement with Employee to provide an incentive to Employee [**] and remain employed by the Company through the dates noted in Sections 1 and 2, below. These dates will be known as the Retention Dates and [**] Bonus Earned Date, as applicable.

Now, therefore, Employee and the Company agree as follows:

1. [**] Bonus. Provided Employee satisfies all the Conditions to Earning a Bonus described in Paragraph 3, below (including its subparts), Employee is eligible to receive a [**] Bonus in the amount shown below, less all applicable state and federal taxes and withholdings:

- [**] Bonus Earned Date - December 15, 2023: **\$100,000.00**

If Employee resigns Employee’s employment for any reason or is terminated for Cause prior to the [**] Bonus Earned Date, Employee becomes ineligible to earn the [**] Bonus set forth in this Agreement. For purposes of this Agreement, termination for “Cause” has the same meaning used in Employee’s Change of Control and Severance Agreement, dated April 23, 2021 (the “CCSA”).

2. Retention Bonus. Provided Employee satisfies all the Conditions to Earning a Bonus described in Paragraph 3, below (including its subparts), Employee is eligible to receive Retention Bonuses in the form of (a) two lump sum cash payments, and (b) a grant of restricted stock unit shares (RSUs), in the amounts shown below as of the applicable Retention Date, less all applicable state and federal taxes and withholdings:

- Retention Date 1 - March 15, 2024: **\$114,750.00**
- Retention Date 2 - August 15, 2024: **229,500 Shares of RSUs**, vesting as of August 15, 2024
- Retention Date 3 - August 16, 2024: **\$114,750.00**

The grant of RSUs under this Agreement, if any, is subject to the terms and conditions of Invitae’s 2015 Stock Incentive Plan and the applicable Stock Award Agreement. Any shares granted to Employee in connection with this Agreement will be canceled if this Agreement is not fully executed by both Employee and the Company.

Employee must be employed at the Company on each Retention Date to qualify for the applicable Retention Bonus under this Agreement. If Employee is terminated (with or without Cause) or resigns their

employment prior to any Retention Date, Employee becomes ineligible to earn any future Retention Bonuses pursuant to this Agreement.

3. Conditions to Earning a Bonus. Employee will earn a Retention Bonus and/or a [**] Bonus if all of the following conditions are met as of each applicable Retention Date and/or [**] Bonus Earned Date, subject to all other terms of this Agreement:

3.1

(a) *For purposes of earning the [**] Bonus:* Employee remains actively employed by the Company through the [**] Bonus Earned Date in Employee's current position, unless Employee is offered and accepts a different role/position with the Company, or is terminated by the Company not for Cause (as defined in the CCSA) prior to the [**] Bonus Earned Date; and

(b) *For purposes of earning one or more Retention Bonuses:* Employee remains actively employed by the Company through the applicable Retention Date in Employee's current position, unless Employee is offered and accepts a different role/position with the Company; and

3.2 Employee faithfully and diligently performs the duties of Employee's position, and such other duties as may be assigned from time to time; and

3.3 Employee faithfully and diligently assists the Company in all of its efforts to complete the [**] in a timely manner up to and through the [**] Bonus Earned Date, including maintaining total confidentiality regarding the [**] (except as the Company permits Employee to disclose); and

3.4 Employee complies with all continuing obligations to the Company, including without limitation, the applicable Employee Manual and Code of Business Conduct and Ethics, and any agreements regarding Company Confidential Information or Trade Secrets; and

3.5 Employee keeps confidential until the [**] Bonus Earned Date the existence and terms of this Agreement and does not discuss it with anyone other than Employee's People & Culture Business Partner, and, in confidence, Employee's spouse, tax and/or legal advisor (except to the extent the terms of this Agreement are publicly disclosed by the Company) or as required by applicable law.

4. Timing of Payments. If a cash Retention Bonus and/or a [**] Bonus is earned by the Employee in accordance with Paragraphs 1 through 3 above, the applicable amount will be paid in a lump sum, less applicable taxes and withholdings, within fifteen (15) days after the applicable Retention Date and/or [**] Bonus Earned Date. The vesting of any RSUs earned by the Employee in accordance with Paragraphs 2 and 3 above is subject to the terms and conditions of Invitae's 2015 Stock Incentive Plan and the applicable Stock Award Agreement; the RSUs will be fully vested and will be released per standard timelines.

5. At-Will Employment. Employee understands and agrees that Employee is and will continue to be an at-will employee of the Company. The Company reserves the right to terminate Employee's employment at any time with or without cause or prior notice, except as provided in the CCSA.

6. Applicable Law. The validity, interpretation and performance of this Agreement shall be construed and interpreted according to the laws of the United States of America and the State in which Employee performed work for the Company during the period in which this Agreement was in effect.

7. Entire Agreement. This Agreement represents the complete understanding of the Company and Employee with respect to the subject matter hereof and supersedes all prior and contemporaneous discussions and agreements, whether written or oral, between any parties with respect to such subject matter. This Agreement shall be the exclusive agreement for the determination of any payments due to the Employee as described herein.

8. Modification, Waiver, & Amendment. No modification of or amendment to this Agreement will be effective unless in a writing signed by both the Company and Employee. No oral waiver, amendment, or modification will be effective under any circumstances whatsoever.

* * *

The parties to this Agreement have read the foregoing Agreement and fully understand each and every provision contained therein. Wherefore, the parties have executed this Agreement on the dates shown below.

Date: October 19, 2023 By: /s/ Tom Brida

Name: Tom Brida

Date: October 19, 2023 By: /s/ Ken Knight

Ken Knight
Invitae Corporation

October 12, 2023

David Sholehvar

Re: Offer of Employment with Invitae Corporation

Dear David,

Congratulations! It is with great pleasure to invite you to join the Invitae team. We look forward to having you join us on **November 13, 2023**.

The terms of our offer are as follows:

- 1. Duties.** As a(n) **Regular, full-time** employee, your role will be **Chief Operating Officer**. As Invitae's business evolves, your job responsibilities are subject to change. During your employment, you will devote your best efforts and your full business time, skill and attention to your Invitae job duties.
 - 2. Location.** This will be a remote position.
 - 3. Salary.** Invitae will pay you a base salary of **\$460,000.00** per year, less all deductions and withholdings that apply. We will pay you according to Invitae's standard payroll practices, as they may change from time to time. The company may modify your compensation during the course of your employment.
 - 4. Sign-on Bonus.** In addition, you will receive a one-time sign-on bonus in the gross amount of **\$150,000.00**, less applicable employment taxes and withholdings. Your sign-on bonus will be payable with your initial paycheck following your commencement of employment at Invitae. If you resign your employment for any reason or are terminated for cause within twelve (12) months following your start date, you will be required to repay Invitae the entirety of your sign-on bonus. For purposes of this Paragraph 4, termination "for cause" shall have the same meaning as set forth in your Invitae Corporation Change of Control and Severance Agreement (the "CCSA").
 - 5. Retention Bonus.** You will also be provided a separate Retention Bonus Agreement setting forth the terms and conditions under which you may be eligible to earn a Retention Bonus in connection with your employment with Invitae, provided you satisfy the conditions set forth therein.
 - 6. Incentive Compensation.** Upon commencement of employment, you will be eligible to participate in the Invitae 2023 Management Incentive Compensation Plan (the "Plan"), subject to the terms of the Plan. The target award for your role is equal to 100% of your annual base salary on a pro-rated basis for 2023, or **\$76,700**. Eligibility to participate in the Plan and actual award amounts are not guaranteed and are determined
-

at sole the discretion of the independent members of Invitae's Board of Directors (the "Board") or the Board's Compensation Committee.

7. Equity. Invitae will grant you **850,000 shares of restricted stock units (RSUs)**. RSUs will vest over a 3-year period, both subject to the terms and conditions of Invitae's 2015 Stock Incentive Plan and the applicable Stock Award Agreement.

8. Benefits. If you choose to enroll, health coverage will begin on the 1st of the following month (e.g., if you start April 22nd, your medical benefits go live May 1st.) You will be eligible to participate in Invitae-sponsored medical and other employee benefits programs. For additional information on Invitae's benefits package, please refer to the Employee Benefits summary enclosed with this letter. We will provide further details at your New Hire Orientation, to be scheduled soon after your first day on the job. The company may, from time to time, change these benefits.

9. Background and Reference Check. This offer of employment is contingent upon satisfactory results of a background and reference check to be performed pursuant to your written authorization.

10. Confidentiality Agreement. As a condition of your employment, you will be expected to sign Invitae's standard At-Will Employment, Confidential Information, Invention Assignment and Arbitration Agreement.

11. At-Will Employment. Your employment with Invitae will be "at will." This means that either you or Invitae may terminate your employment at any time, with or without cause, subject to the terms and conditions set forth in your CCSA. Any contrary representations or agreements which may have been made to you are superseded by this offer letter. The "at will" term of your employment can only be changed in writing signed by you and Invitae.

12. Arbitration.

(a) Agreement to Arbitrate All Disputes. To ensure the timely and economical resolution of disputes that may arise between you and Invitae, both you and Invitae mutually agree that pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by applicable law, you will submit solely to final, binding and confidential arbitration any and all disputes, claims, or causes of action arising from or relating to: **(i)** the negotiation, execution, interpretation, performance, breach or enforcement of this Agreement; or **(ii)** your employment with Invitae (including but not limited to all statutory claims); or **(iii)** the termination of your employment with Invitae (including but not limited to all statutory claims). **BY AGREEING TO THIS ARBITRATION PROCEDURE, BOTH YOU AND INVITAE WAIVE THE RIGHT TO RESOLVE ANY SUCH DISPUTES THROUGH A TRIAL BY JURY OR JUDGE OR THROUGH AN ADMINISTRATIVE PROCEEDING.**

(b) Arbitrator Authority. The Arbitrator shall have the sole and exclusive authority to determine whether a dispute, claim or cause of action is subject to arbitration under this Arbitration section and to determine any procedural questions which grow out of such disputes, claims or causes of action and bear on their final disposition.

(c) Individual Capacity Only. All claims, disputes, or causes of action under this Arbitration section, whether by you or Invitae, must be brought solely in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The Arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences in this paragraph are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration.

(d) Arbitration Process. Any arbitration proceeding under this Arbitration section shall be presided over by a single arbitrator and conducted by JAMS, Inc. ("JAMS") in San Francisco under the then applicable JAMS rules for the resolution of employment disputes (available upon request and also currently available at <http://www.jamsadr.com/rules-employment-arbitration/>). You and Invitae both have the right to be represented by legal counsel at any arbitration proceeding, at each party's own expense. The Arbitrator shall: **(i)** have the authority to compel adequate discovery for the resolution of the dispute; **(ii)** issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award; and **(iii)** be authorized to award any or all remedies that you or Invitae would be entitled to seek in a court of law. Invitae shall pay all JAMS arbitration fees in excess of the amount of court fees that would be required of you if the dispute were decided in a court of law.

(e) Excluded Claims. This Arbitration section shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and such applicable law is not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "**Excluded Claims**"). In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration.

(f) Injunctive Relief and Final Orders. Nothing in this Arbitration section is intended to prevent either you or Invitae from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any final award in any arbitration proceeding hereunder may be entered as a judgment in the federal and state courts of any competent jurisdiction and enforced accordingly.

13. Miscellaneous. This letter along with the documents referenced herein and the CCSA and documents referenced therein states the complete and exclusive

terms and conditions of your offer and supersedes any other agreements, whether written or oral. By joining Invitae, you are agreeing to abide by all Invitae policies and procedures as they are established. The terms of this offer and your employment with Invitae will be governed in all aspects by the laws of the state(s) in which you perform work for Invitae. As required by law, this offer is subject to satisfactory proof of your right to work in the United States.

We look forward to having you join us on **November 13, 2023**. If you wish to accept this offer under the terms and conditions described above please sign and date this letter and return it to me by **October 17, 2023** If you have any questions about the terms of this offer, please contact me.

Best Regards,

/s/ John Curran

John Curran
Head of Talent Acquisition
Invitae Corporation

I have read this offer letter. I understand and agree to its terms.

/s/ David Sholehvar

David Sholehvar

Signed Date: October 13, 2023

RETENTION BONUS AGREEMENT

This Retention Bonus Agreement (“Agreement”) is made and entered into as of the date of execution by all parties as indicated below, by and between **Invitae Corporation** (the “Company”) and **David Sholehvar**.

(“Employee”) with respect to the following facts:

A. Employee will be and/or is currently employed by the Company as **Chief Operating Officer**.

B. The Company recognizes and values Employee’s contributions to the Company and is interested in retaining Employee in its employ. Accordingly, the Company enters into this Agreement with Employee to provide an incentive to Employee to remain employed by the Company until the date noted in Section 1, below. This date will be known as the Retention Date.

Now, therefore, Employee and the Company agree as follows:

1. Retention Bonus. Provided Employee satisfies all the Conditions to Earning a Bonus described in Paragraph 2, below (including its subparts), as of the Retention Date, Employee will earn a Retention Bonus in the amount shown below, less all applicable state and federal taxes and withholdings:

- Retention Date – May 13, 2024: \$150,000.00

2. Conditions to Earning a Bonus. Employee will earn a Retention Bonus if all of the following conditions are met as of the Retention Date, subject to all other terms of this Agreement:

2.1 Employee remains employed by the Company through the Retention Date in Employee’s current position, unless Employee is offered and accepts a different role/position with the Company; and

2.2 Employee faithfully and diligently performs the duties of Employee’s position, and such other duties as may be assigned from time to time; and

2.3 Employee complies with all continuing obligations to the Company, including without limitation, the applicable Employee Manual and Code of Ethics, and any agreement regarding Company Confidential Information or Trade Secrets.

3. Timing of Payments. If a Retention Bonus is earned by the Employee in accordance with Paragraphs 1 and 2 above, the amount will be paid in a lump sum, less applicable taxes and withholdings, within 30 days after the Retention Date.

4. Repayment Obligation. If Employee resigns his employment for any reason or is terminated for cause within the twelve (12) months following the Retention Date, Employee will be required to repay Invitae the applicable Retention Bonus in accordance with the table set forth in Section 5, below. For purposes of the Repayment Obligation, termination “for cause” means misconduct with respect to Employee’s employment or otherwise relating to the business of Invitae; material neglect of duties; falsification of any employment or other records; improper use or disclosure of Invitae’s trade secrets or confidential information; violation of or failure to comply with Invitae’s Employee Manual and/or Code of Business Conduct and Ethics; or other conduct that is likely to have an adverse effect on the name or public image of Invitae.

5. Repayment Calculation.

Resignation/Termination During Month No.	Repayment Percentage
1	100%
2	91.67%
3	83.33%
4	75%
5	66.67%
6	58.33%
7	50%
8	41.67%
9	33.33%
10	25%
11	16.67%
12	8.33%
After 12	0%

6. At-Will Employment. Employee understands and agrees that Employee is and will continue to be an at-will employee of the Company. The Company reserves the right to terminate Employee's employment at any time with or without cause or prior notice.

7. Applicable Law. The validity, interpretation and performance of this Agreement shall be construed and interpreted according to the laws of the United States of America and the State in which Employee performed work for the Company during the period in which this Agreement was in effect.

8. Entire Agreement. This Agreement constitutes the entire agreement between Employee and the Company with regard to a Retention Bonus for the time period at issue herein, and supersedes any and all prior agreements, whether written or oral, between the parties regarding retention bonuses. This Agreement shall be the exclusive agreement for the determination of any retention payments due to the Employee. No modification of or amendment to this Agreement will be effective unless in a writing signed by both the Company and Employee. No oral waiver, amendment, or modification will be effective under any circumstances whatsoever.

* * *

The parties to this Agreement have read the foregoing Agreement and fully understand each and every provision contained therein. Wherefore, the parties have executed this Agreement on the dates shown below.

Date: 2023-Oct-13 By: /s/ David Sholehvar
David Sholehvar

Date: 2023-Oct-13 By: /s/ Desarie French
Desarie French
Invitae Corporation

INVITAE CORPORATION

CHANGE OF CONTROL AND SEVERANCE AGREEMENT

This Change of Control Severance Agreement (this “Agreement”) is made and entered into effective as of _____ (the “Effective Date”), by and between _____ (“Executive”) and Invitae Corporation, a Delaware corporation (the “Company”). Certain capitalized terms used in this Agreement are defined in Section 1 below.

RECITALS

A. It is expected that the Company from time to time will consider the possibility of a Change of Control. The Board of Directors of the Company (the “Board”) recognizes that such consideration can be a distraction to Executive and can cause Executive to consider alternative employment opportunities.

B. The Board believes that it is in the best interests of the Company and its shareholders to provide Executive with an incentive to continue Executive’s employment and to maximize the value of the Company upon a Change of Control for the benefit of its shareholders.

C. In order to provide Executive with enhanced financial security and sufficient encouragement to remain with the Company notwithstanding the possibility of a Change of Control, the Board believes that it is imperative to provide Executive with certain severance and other benefits upon Executive’s termination of employment in connection with a Change of Control.

D. The Board also believes it is in the best interests of the Company and its shareholders to provide Executive with severance upon an involuntary termination other than in connection with a Change of Control.

AGREEMENT

In consideration of the mutual covenants herein contained and the continued employment of Executive by the Company, the parties agree as follows:

1. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) Cause. “Cause” shall mean Executive’s (i) commission of a felony, an act involving moral turpitude, or an act constituting common law fraud, and which has an adverse effect on the business or affairs of the Company or its affiliates or stockholders; (ii) intentional or willful misconduct or refusal to follow the lawful instructions of the Board or the Chief Executive Officer that is not cured within thirty (30) days following written notice from the Board or the Chief Executive Officer; (iii) commission of any violation of a company policy that has a material adverse effect on the business or reputation of the Company or (iv) intentional

breach of Company confidential information obligations which has an adverse effect on the Company or its affiliates or stockholders. For these purposes, no act or failure to act shall be considered “intentional or willful” unless it is done, or omitted to be done, in bad faith without a reasonable belief that the action or omission is in the best interests of the Company.

(b) Change of Control. “Change of Control” shall mean the occurrence of any of the following events:

(i) A change in the composition of the Board occurs, as a result of which fewer than one-half of the incumbent directors are directors who either:

(A) had been directors of the Company on the “look-back date” (as defined below) (the “original directors”); or

(B) were elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the aggregate of the original directors who were still in office at the time of the election or nomination and the directors whose election or nomination was previously so approved (the “continuing directors”);

provided, however, that for this purpose, the “original directors” and “continuing directors” shall not include any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or

(ii) Any “person” (as defined below) who by the acquisition or aggregation of securities, is or becomes the “beneficial owner” (as defined in Rule 13d-3 under the Securities Exchange Act of 1934 (the “Exchange Act”)), directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company’s then outstanding securities ordinarily (and apart from rights accruing under special circumstances) having the right to vote at elections of directors (the “Base Capital Stock”); except that any change in the relative beneficial ownership of the Company’s securities by any person resulting solely from a reduction in the aggregate number of outstanding shares of Base Capital Stock, and any decrease thereafter in such person’s ownership of securities, shall be disregarded until such person increases in any manner, directly or indirectly, such person’s beneficial ownership of any securities of the Company; or

(iii) the consummation of a merger or consolidation of the Company or a Subsidiary of the Company with or into another entity or any other corporate reorganization, if persons who were not stockholders of the Company immediately prior to such merger, consolidation or other reorganization own immediately after such merger, consolidation or other reorganization 50% or more of the voting power of the outstanding securities of each of:

(A) the Company (or its successor) and

(B) any direct or indirect parent corporation of the Company (or its successor); or

- (iv) The sale, transfer or other disposition of all or substantially all of the Company's assets.

For purposes of subsection 1(b)(i) above, the term "look-back date" shall mean the date 24 months prior to the date of the event that may constitute a Change of Control.

For purposes of subsection 1(b)(ii) above, the term "person" shall have the same meaning as when used in Sections 13(d) and 14(d) of the Exchange Act but shall exclude (1) a trustee or other fiduciary holding securities under an employee benefit plan maintained by the Company or a parent or subsidiary and (2) a corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of the stock.

Any other provision of this Section 1(b) notwithstanding, a transaction shall not constitute a Change of Control if its sole purpose is to change the state of the Company's incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction, and a Change of Control shall not be deemed to occur if the Company files a registration statement with the United States Securities and Exchange Commission for the initial or secondary public offering of securities or debt of the Company to the public.

- (c) Disability. "Disability" shall mean "disability" within the meaning of Section 22(e)(3) of the Code

(d) Equity Award. "Equity Award" shall mean Executive's awards of options, stock appreciation rights, restricted shares or stock units with respect to the Company or its successor, or the direct or indirect parent of either, or of any deferred compensation into which such stock options, stock appreciation rights, restricted shares or stock units were converted upon or prior to a Change of Control.

- (e) Involuntary Termination. "Involuntary Termination" shall mean:

(i) a material reduction in Executive's title, duties, authorities or responsibilities relative to Executive's title, duties, authorities, or responsibilities as of the Effective Date without the Executive's consent;

(ii) without Executive's express written consent, a reduction by the Company of Executive's base compensation of more than ten percent (10%), unless such reduction in base compensation is part of a general reduction in compensation applicable to senior executives of the Company;

(iii) without Executive's express written consent, the relocation of Executive's principal place of employment to a facility or a location more than fifty (50) miles from its location as of the Effective Date or, on or following a Change of Control, from its location immediately prior to such Change of Control;

(iv) any termination of Executive by the Company which is not effected for Cause; or

(v) the failure of the Company to obtain the assumption of this Agreement or any other agreement between the Company and Executive by any successors contemplated in Section 10 below.

A termination shall not be considered an “Involuntary Termination” unless Executive provides notice to the Company of the existence of the condition described in subsections (i), (ii), (iii) or (iv) above within ninety (90) days of the initial existence of such condition, the Company fails to remedy the condition within thirty (30) days following the receipt of such notice, and Executive terminates employment within one-hundred eighty (180) days following the initial existence of such condition. A termination due to death or disability shall not be considered an Involuntary Termination.

(f) Termination Date. “Termination Date” shall mean Executive’s “separation from service” within the meaning of that term under Section 409A of the Internal Revenue Code of 1986, as amended (the “Code”).

2. Term of Agreement. This Agreement shall terminate on the third anniversary of the Effective Date, unless mutually renewed by the parties.

3. At-Will Employment. The Company and Executive acknowledge that Executive’s employment is and shall continue to be at-will, as defined under applicable law.

4. Change of Control Related Benefits

(a) Effect of Change of Control on Performance-Based Equity Awards. If Executive is either employed at the time of a Change of Control or Executive’s employment with the Company terminates as a result of an Involuntary Termination on or within three (3) months prior to a Change of Control, and provided that in the case of such Involuntary Termination the Executive signs and does not revoke a release in a form approved by the Company (a “Release”) that has become irrevocable within sixty (60) days following the later of the Change of Control or the Termination Date, then all of Executive’s Equity Awards subject to vesting based on performance shall have their performance criteria deemed satisfied at 100% of target for any unfinished performance period and such Equity Awards will convert to time-based vesting on such vesting schedule as specified in the applicable Equity Award agreement, subject to the provisions of Section 4(b). The portion of any performance-based Equity Award for which the performance condition is not deemed satisfied pursuant to this Section 4(a) (if any) will be forfeited. The effective date of the foregoing vesting credit and forfeiture will be the date of the Change of Control.

(b) Involuntary Termination in Connection with a Change of Control. If Executive’s employment with the Company terminates as a result of an Involuntary Termination either on or at any time within twelve months (12) months after a Change of Control, or within three (3) months prior to a Change of Control, and Executive signs and does not revoke a

Release that has become irrevocable within sixty (60) days following the later of the Change of Control or the Termination Date, then Executive shall be entitled to the following severance benefits, subject to Section 9 below:

- (i) 100% of Executive's annual base salary (as in effect prior to any reduction that constitutes a basis for Involuntary Termination pursuant to this Agreement), payable in a lump sum on the sixtieth (60th) day following the later of the Termination Date or the Change of Control;
- (ii) any earned but unpaid annual bonus for any annual bonus period which had ended prior to the Termination Date, which amount shall be paid at such time as annual bonuses are paid to other senior executives of the Company;
- (iii) all of Executive's outstanding Equity Awards subject to time-based vesting (including any Equity Awards converted to time-based vesting pursuant to Section 4(a)) will become fully vested and exercisable; provided, however, that notwithstanding any contrary term of the Equity Award agreement, if Executive is entitled to accelerated vesting under this Section 4(b) as a result of an Involuntary Termination within three (3) months prior to a Change of Control: (1) the portion of the Equity Award subject to such accelerated vesting shall not be forfeited or terminated upon the Termination Date pending the Change of Control, (2) the accelerated vesting shall be deemed to take place immediately prior to the effective date of the Change of Control, and (3) the period within which the Equity Award may be exercised following the Termination Date, if applicable, will expire no less than one (1) month following the effective date of the Change of Control (but no later than the expiration of the term of the Equity Award); and
- (iv) a lump sum payment equal to twelve (12) months of premiums under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or corresponding provision of state law ("COBRA") for health insurance coverage for Executive and Executive's eligible dependents, at the same level and for the same eligible dependents covered as of Executive's Termination Date. If Executive is eligible and chooses to continue health coverage through COBRA, Executive is solely responsible for timely electing COBRA continuing coverage and for making all COBRA premium payments.

5. Involuntary Termination Apart from a Change of Control. If Executive's employment with the Company terminates as a result of an Involuntary Termination that occurs more than three (3) months prior to or twelve (12) months after a Change of Control, and Executive signs and does not revoke a Release that has become irrevocable within sixty (60) days following the Termination Date, then Executive shall be entitled to the following severance benefits, subject to Section 9 below:

- (a) 100% of Executive's annual base salary (as in effect prior to any reduction that constitutes a basis for Involuntary Termination pursuant to this Agreement), payable in a lump sum on the sixtieth (60th) day following the Termination Date;

(b) any earned but unpaid annual bonus for any annual bonus period which had ended prior to the Termination Date, which amount shall be paid at such time as annual bonuses are paid to other senior executives of the Company; and

(c) a lump sum payment equal to twelve (12) months of premiums under COBRA for health insurance coverage for Executive and Executive's eligible dependents, at the same level and for the same eligible dependents covered as of Executive's Termination Date. If Executive is eligible and chooses to continue health coverage through COBRA, Executive is solely responsible for timely electing COBRA continuing coverage and for making all COBRA premium payments.

6. Mutually Exclusive Benefits. For the avoidance of doubt, the benefits afforded under Sections 4(b) and 5 are mutually exclusive. If Executive has an Involuntary Termination within three (3) months prior to a Change of Control and becomes entitled to cash severance pursuant to Section 4(b), but already received cash severance pursuant to Section 5, the amount of the cash severance payable pursuant to Section 4(b) shall be offset by the amount already paid, subject to compliance with Section 409A of the Code.

7. Accrued Wages and Vacation; Expenses. If Executive's employment with the Company terminates, without regard to the reason for, or the timing of, Executive's termination of employment, then (i) the Company shall pay Executive any unpaid wages due for periods prior to the Termination Date; (ii) the Company shall pay Executive all of Executive's accrued and unused vacation through the Termination Date; and (iii) following submission of proper expense reports by Executive, the Company shall reimburse Executive for all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the Termination Date. These payments shall be made promptly upon termination and within the period of time mandated by law.

8. Limitation on Payments. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) would be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then Executive's benefits under this Agreement shall be either:

(a) delivered in full or

(b) delivered as to such lesser extent which would result in no portion of such benefits being subject to the Excise Tax,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Executive on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code.

Unless the Company and Executive otherwise agree in writing, any determination required under this Section 8 shall be made in writing by the Company's independent public

accountants (the “Accountants”), whose determination shall be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required by this Section 8, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section 8. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 8. In the event that a reduction is required, the reduction shall be applied first to any benefits that are not subject to Section 409A of the Code, and then shall be applied to benefits (if any) that are subject to Section 409A of the Code, with the benefits payable latest in time subject to reduction first.

9. Section 409A; Delayed Commencement of Benefits. The parties intend that any amounts payable hereunder comply with or are exempt from Section 409A of the Code (“Section 409A”), and this Agreement shall be administered accordingly. In the event that any changes to this Agreement or any additional terms are required to ensure that a payment is either exempt from or complies with Section 409A so that the penalty taxes under Section 409A(a)(1)(B) are not applied, you hereby agree that the Company may make such change or incorporate such terms (by reference or otherwise) without your consent. Each payment contemplated by this Agreement will be treated as a separate payment for purposes of Section 409A. Notwithstanding anything herein to the contrary, the Company shall have no liability to the Executive or to any other person if the payments and benefits provided in this Agreement that are intended to be exempt from or compliant with Section 409A are not so exempt or compliant, as applicable.

10. Successors.

(a) Company’s Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company’s business and/or assets shall assume the Company’s obligations under this Agreement and agree expressly to perform the Company’s obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term “Company” shall include any successor to the Company’s business and/or assets which executes and delivers the assumption agreement described in this subsection (a) or which becomes bound by the terms of this Agreement by operation of law.

(b) Executive’s Successors. Without the written consent of the Company, Executive shall not assign or transfer this Agreement or any right or obligation under this Agreement to any other person or entity. Notwithstanding the foregoing, the terms of this Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable by, Executive’s personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

11. Notices.

(a) General. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of Executive, mailed notices shall be addressed to Executive at the home address which he most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(b) Notice of Termination. Any termination by the Company for Cause or by Executive as a result of an Involuntary Termination shall be communicated by a notice of termination to the other party hereto given in accordance with this Section 11. Such notice shall indicate the specific termination provision in this Agreement relied upon, shall set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and shall specify the Termination Date (which shall be not more than thirty (30) days after the giving of such notice). The failure by Executive to include in the notice any fact or circumstance which contributes to a showing of Involuntary Termination shall not waive any right of Executive hereunder or preclude Executive from asserting such fact or circumstance in enforcing Executive's rights hereunder, subject to the requirements of Section 1(e).

12. Arbitration. Any controversy involving the construction or application of any terms, covenants or conditions of this Agreement, or any claims arising out of any alleged breach of this Agreement, will be governed by the rules of the American Arbitration Association and submitted to and settled by final and binding arbitration in San Francisco, California, except that any alleged breach of Executive's confidential information obligations shall not be submitted to arbitration and instead the Company may seek all legal and equitable remedies, including without limitation, injunctive relief.

13. Miscellaneous Provisions.

(a) No Duty to Mitigate. Executive shall not be required to mitigate the amount of any payment contemplated by this Agreement, nor shall any such payment be reduced by any earnings that Executive may receive from any other source.

(b) Waiver. No provision of this Agreement may be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Integration. This Agreement supersedes and replaces any prior agreements, representation or understandings, whether written, oral, express or implied, between

Executive and the Company and constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(f) Employment Taxes. All payments made pursuant to this Agreement shall be subject to withholding of applicable income and employment taxes.

(g) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY:

INVITAE CORPORATION

By: _____

Name: _____

Title: _____

EXECUTIVE:

Signature

Printed Name:

Title:

EXHIBIT 15

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 13, 2023



Invitae Corporation

(Exact name of the registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. employer
identification number)

1400 16th Street, San Francisco, California 94103
(Address of principal executive offices, including zip code)

(415) 374-7782
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On December 13, 2023, Invitae Corporation (the “Company”) announced it has divested the assets of its Ciitizen patient-centric consumer health tech platform. The Company also announced plans to reduce its operating expenses through a workforce reduction and other cost saving initiatives, which include streamlining processes across its core platforms and optimizing its technology, professional services and other spending. The divestiture and the announced plans will decrease the Company’s workforce by approximately 15%. In combination with the Ciitizen transaction, these initiatives are anticipated to result in one-time severance related payments of approximately \$10 million. In addition, the Company expects to incur non-cash charges which it is currently not able to estimate. The Company will file an amendment to this Current Report on Form 8-K, as necessary, when such charges become estimable. The Company plans to recognize these charges in its financial statements for the quarters ending December 31, 2023 and March 31, 2024.

Item 8.01 Other Events.

On December 13, 2023, the Company issued a press release describing the Ciitizen divestiture and plans to reduce operating expenses (the “Press Release”). The full text of the Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the Company’s strategic objectives and anticipated outcomes; the divestiture of and future partnership opportunities with Ciitizen; and operational streamlining, cost reduction initiatives and their projected impact on the Company’s financial and operational performance. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the availability of and need for capital; the ability to service the Company’s debt obligations; the successful execution and anticipated benefits of the divestiture and cost reduction strategies; potential unforeseen costs or challenges associated with these strategies; the risk that the disruption resulting from these activities may harm the Company’s business, market share or its relationship with customers or potential customers; the impact of inflation and the current economic environment on the Company’s business; and the other risks set forth in the reports filed by the Company in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. These forward-looking statements speak only as of the date hereof, and Invitae Corporation disclaims any obligation to update these forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Invitae Corporation dated December 13, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: December 14, 2023

INVITAE CORPORATION

By: /s/ Thomas R. Brida
Name: Thomas R. Brida
Title: General Counsel

EXHIBIT 16

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 11, 2024



Invitae Corporation

(Exact name of the registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. employer
identification number)

1400 16th Street, San Francisco, California 94103
(Address of principal executive offices, including zip code)

(415) 374-7782
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

As previously disclosed by Invitae Corporation (the “Company”), the Company has agreed to enter into a transaction support agreement with certain of its lenders and it has also committed to certain cost saving initiatives as part of the Company’s efforts to reduce operating expenses. Given the amount of work required to undertake these efforts, the board of directors of the Company (the “Board”) determined that it was in the best interest of the Company to reinforce and provide incentive for the continued attention and dedication of certain key employees to their duties of employment.

Accordingly, on January 11, 2024, the Board approved a retention program, pursuant to which certain of its executive officers, including those identified herein (the “Officers”), received retention payments (the “Retention Program”). In connection with the adoption of the Retention Program, the Company entered into Retention Agreements (“Retention Agreements”) with each of the Officers, pursuant to which each Officer received a one-time cash payment in the following amounts: Kenneth D. Knight (\$1,625,000), Ana Schrank (\$1,740,000) and Thomas R. Brida (\$1,425,000).

If an Officer is terminated for cause or resigns from employment without good reason (as defined in the Retention Agreements) prior to January 14, 2025, such Officer will be required to repay an after-tax portion of the retention payment pursuant to the terms set forth in the Retention Agreements. In addition, pursuant to the Retention Agreements, each Officer agreed to forego (i) their participation in the 2024 management incentive compensation plan and (ii) their eligibility to receive a 2024 long-term incentive equity award. Mr. Brida also agreed to forego a total of \$629,500 in retention payments that were previously awarded to him, but not yet paid.

The foregoing description of the material terms of the Retention Agreements is not intended to be complete and is qualified in its entirety by reference to the form of Retention Agreement attached hereto as Exhibit 10.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	Form of Retention Agreement.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: January 18, 2024

INVITAE CORPORATION

By: /s/ Thomas R. Brida
Name: Thomas R. Brida
Title: General Counsel

[TO BE PLACED ON COMPANY LETTERHEAD]

Personal and Confidential

January [●], 2024

[Employee Name]
[Address]

Re: Retention Bonus

Dear [●]:

On behalf of Invitae Corporation (the “*Company*”), I am pleased to offer you an opportunity to receive a retention bonus of \$_____ (the “*Retention Bonus*”) if you agree to the terms and conditions of this letter agreement (this “*Agreement*”). To receive this Retention Bonus, you must execute and return a copy of this Agreement to the Company as described on the signature page below by no later than January [], 2024. Unless otherwise defined herein, all terms used herein with their initial letter capitalized shall have the meanings given to such terms in Section 3.

1. **Retention Bonus.** Subject to the terms and conditions set forth herein, you will be paid the Retention Bonus in a cash lump sum payment on or about January [], 2024. As a condition to receiving the Retention Bonus, you hereby waive any and all rights in respect of the compensation arrangements described on Exhibit A attached hereto and agree that such waiver shall not be considered to be a breach of any other agreement with the Company Group or constitute “Good Reason” (or similar term) under any such other agreement. For the sake of clarity, the Retention Bonus and this Agreement do not affect payments under any other retention arrangement that is not listed on Exhibit A.

2. **Vesting/Repayment Conditions.**

(a) **Vesting.** Your Retention Bonus will vest and no longer be subject to repayment pursuant to Section 2(b) on the applicable Vesting Date if you are employed by the Company Group on that date. In addition, your Retention Bonus will fully vest and no longer be subject to repayment pursuant to Section 2(b) on the date of your Qualifying Termination before the Vesting Date.

(b) **Repayment.** In the event of your Non-Qualifying Termination before the Vesting Date, you agree to repay 100% of the After-Tax Value of the Unvested Component of your Retention Bonus within 20 days after such termination. For the sake of clarity, you will not be required to repay any portion of your Retention Bonus based on any termination occurring after the Vesting Date.

3. **Definitions.** For purposes of this Agreement:

“*After-Tax Value*” means the portion of your Retention Bonus required to be repaid under Section 2(b) net of any taxes withheld or paid in respect thereof. The Company shall determine the After-Tax Value, which determination shall be final, conclusive and binding for all purposes hereunder.

“*Cause*” has the meaning set forth in the Change in Control Agreement.

“**Company Group**” means the Company and its direct and indirect subsidiaries.

“**Change in Control Agreement**” means the Change in Control and Severance Agreement in effect between you and the Company or, if you are not party to a Change in Control and Severance Agreement, the Form of Change in Control and Severance Agreement, between Invitae Corporation and certain officers filed as Exhibit 10.22 to the Company’s Form 10-K filing for the fiscal year ended December 31, 2022.

“**Disability**” has the meaning set forth in the Change in Control Agreement.

“**Good Reason**” has the same meaning as “Involuntary Termination” as set forth in the Change in Control Agreement.

“**Non-Qualifying Termination**” means any termination of your employment with the Company Group that is not considered to be a Qualifying Termination.

“**Qualifying Termination**” means the termination of your employment with the Company Group (i) by the Company for a reason other than Cause, (ii) by you for Good Reason, (iii) due to your Disability or (iv) due to your death if, and only if, in the case of any termination pursuant to clauses (i), (ii) and (iii), you execute a release of employment related claims in a form to be provided by the Company (the “**Release**”) within the time provided by the Company to do so, and you do not revoke such Release within any time provided by the Company to do so.

“**Unvested Component**” means the portion of your Retention Bonus, if any, that has not vested pursuant to Section 2(a) as of the date of your Non-Qualifying Termination.

“**Vesting Date**” means January 14, 2025.

4. **Withholding Taxes.** All amounts to be paid hereunder shall be subject to and reduced by the amount of all applicable income, employment and other taxes required to be withheld by the Company or any other member of the Company Group under applicable law.

5. **No Right to Continued Employment.** Nothing in this Agreement will confer upon you any right to continued employment with the Company or any member of the Company Group (or any of their respective successors) or interfere in any way with the right of the Company or any member of the Company Group (or any of their respective successors) to terminate your employment at any time or for any reason or to change the terms of your employment in any manner.

6. **Other Benefits.** The Retention Bonus is a special payment to you and will not be taken into account in computing the amount of salary or compensation for purposes of determining any bonus, incentive, pension, retirement, death or other benefit under any other bonus, incentive, pension, retirement, insurance or other employee benefit plan of any member of the Company Group, unless such plan or agreement expressly provides otherwise.

7. **Governing Law.** This Agreement will be governed by, and construed under and in accordance with, the internal laws of the State of Delaware, without reference to rules relating to conflicts of laws.

8. **Entire Agreement; Amendment.** This Agreement constitutes the entire agreement between you and the Company with respect to the Retention Bonus and supersedes any and all prior agreements or understandings between you and the Company with respect to the Retention Bonus, whether written or oral. This Agreement may be amended or modified only by a written instrument executed by you and the Company.

9. **Section 409A.** The Retention Bonus is intended to be exempt from the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (“**Section 409A**”), and accordingly, this Agreement shall be interpreted in a manner consistent therewith. Notwithstanding the foregoing, the Company makes no representations that the Retention Bonus is exempt from, or compliant with, Section 409A and in no event shall any member of the Company Group be liable for all or any portion of any taxes, penalties, interest or other expenses that you may incur on account of non-compliance with Section 409A.

[REMAINDER OF PAGE LEFT INTENTIONALLY BLANK]

This Agreement is intended to be a binding obligation on you and the Company. If this Agreement accurately reflects your understanding as to the terms and conditions of the Retention Bonus, please sign, date, and return a copy of this Agreement to [NAME] at [EMAIL]. You should keep a copy of the executed Agreement for your records.

Very truly yours,

INVITAE CORPORATION

By: _____
Name: _____
Title: _____

ACKNOWLEDGED AND AGREED:

[Employee Name]

Date: _____

Exhibit A – Superseded Arrangements

1. Participation in the 2024 management incentive compensation plan
2. Eligibility to receive a 2024 long-term incentive equity award
3. [Eligibility to receive all unearned cash retention bonuses set forth in the Retention and Bonus Agreement between you and the Company dated October 19, 2023]
4. [Eligibility to receive the Executive Long-Term Retention Payment approved by the Board on April 3, 2023]

EXHIBIT 17

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 17, 2024



Invitae Corporation

(Exact name of the registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. employer
identification number)

1400 16th Street, San Francisco, California 94103
(Address of principal executive offices, including zip code)

(415) 374-7782
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

On January 17, 2024, Invitae Corporation (the “Company”) entered into and subsequently closed an Asset Purchase Agreement (the “Agreement”) with Natera, Inc., a Delaware corporation (“Natera”).

Pursuant to the terms of the Agreement, the Company sold, and Natera purchased (i) a list of the Company’s customers who are healthcare service providers in the reproductive health category (the “RH Customers”) and (ii) subject to receipt of consents from counterparties thereto, certain contracts with the RH Customers (the “RH Only Contracts”) that relate exclusively to the testing services provided by the Company (each, a “Transferred Contract”), including carrier screening and non-invasive prenatal screening (the “Testing Services”). Natera has also hired certain Invitae employees engaged in the reproductive health category.

In consideration for the purchased assets, Natera (i) has made an upfront payment in cash in the amount of \$10.0 million to Invitae and (ii) will make additional payments up to \$42.5 million, which amount, if any, includes (a) the payment of cash and/or providing litigation-related credits in relation to the previously disclosed case captioned Natera, Inc. v. ArcherDx, Inc. Nos. 20-cv-125-GBW and 20-cv-1047-GBW (the “Natera v. ArcherDx Case”), and (b) a performance-based milestone cash payment, as further described below.

After entry of a final, non-appealable order disposing of all claims in respect of the Natera v. ArcherDx Case, Natera will provide to the Company cash and/or litigation-related credits, if any, for a combined value of up to \$20.0 million. Pursuant to the Agreement, the parties have also agreed that the Company’s liabilities, if any, for past damages for infringing sales of all versions of the Invitae Personalized Cancer Monitoring™ (PCM) product that were found to infringe in the Natera v. ArcherDx Case (but not other versions of PCM) through jury verdict and not beyond (including pre- and post-judgment interest) will be limited to a maximum of \$20.0 million.

Pursuant to the terms of the Agreement, by June 15, 2024, Natera will pay Invitae a milestone payment of up to \$22.5 million based on the volume of Testing Services that Natera is able to retain. The Agreement requires Natera to operate in good faith and use commercially reasonable efforts to maximize such retention. Volume retention is calculated by comparing the number of accessions of non-invasive prenatal screening tests and genetic carrier screening tests performed by Natera for RH Customers during the 30-day period ending on May 16, 2024 against a base accession amount agreed by the parties.

Under the Agreement, Natera will not assume, and Invitae will retain, all liabilities and obligations relating to the Company’s reproductive health business to the extent arising prior to the closing of the transactions contemplated in the Agreement. Further, Natera will assume any liabilities and obligations under Transferred Contracts solely to the extent arising at or after the applicable date the services provided by the Company under any applicable Transferred Contract ends.

The Agreement includes a non-competition covenant pursuant to which until March 18, 2027, the Company may not offer the Testing Services (“Competing Business”); provided that such restriction will not (A) apply to any unaffiliated third party counterparty or such counterparty’s affiliates (other than the Company and its subsidiaries) that may acquire control of the Company; provided further, that such unaffiliated third party counterparty and/or such counterparty’s affiliates (other than the Company and its subsidiaries) either (1) has been engaged in a Competing Business for the 12 months immediately prior to such acquisition of control of the Company or (2) has \$50.0 million or more in gross operating assets or (B) prevent the Company from entering into any partnerships or business relationships with unaffiliated third parties that may be engaged in providing such services.

Pursuant to the Agreement, the Company is also required to use commercially reasonable efforts to assist Natera in obtaining any required consents, approvals or waivers, and in connection with the RH Only Contracts that Natera desires to be assigned or transferred to Natera. In connection with the Agreement, the Company and Natera have also entered into a transition services agreement, pursuant to which the

Company has agreed to provide certain transitional services, including the Testing Services, to Natera through March 17, 2024. Certain limited support services, including with respect to communications with RH Customers and patients, forwarding kits the Company receives and customer transition support, will continue to be provided to Natera until no later than July 15, 2024.

Item 2.01 Completion of Acquisition or Disposition of Assets.

The information set forth above under Item 1.01 of this Current Report on Form 8-K is incorporated herein by reference.

Item 2.05 Costs Associated with Exit or Disposal Activities.

In connection with the consummation of the transaction described under Item 1.01 of this Current Report on Form 8-K, the Company reduced its operating expenses through a workforce reduction. The Company expects to incur non-cash charges which it is currently not able to estimate. The Company will file an amendment to this Current Report on Form 8-K, as necessary, when such charges become estimable.

Item 7.01 Regulation FD Disclosure.

On January 22, 2024, the Company issued a press release announcing the sale of certain reproductive health assets to Natera (the "Press Release"). The full text of the Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Exhibit 99.1 shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the divestiture of the Company's reproductive health business and its projected impact on the Company's financial and operational performance; the effect of the pending patent litigation; the Company's cost reduction initiatives and their projected impact on the Company's financial and operational performance. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the availability of and need for capital; the ability to service the Company's debt obligations; the successful execution and anticipated benefits of the divestiture and cost reduction strategies; potential unforeseen costs or challenges associated with these strategies; the risk that the disruption resulting from these activities may harm the Company's business, market share or its relationship with customers or potential customers; the impact of inflation and the current economic environment on the Company's business; and the other risks set forth in the reports filed by the Company in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. These forward-looking statements speak only as of the date hereof, and Invitae Corporation disclaims any obligation to update these forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Invitae Corporation dated January 22, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: January 22, 2024

INVITAE CORPORATION

By: /s/ Thomas R. Brida
Name: Thomas R. Brida
Title: General Counsel

EXHIBIT 18

Filed Under Seal

EXHIBIT 19

Filed Under Seal

EXHIBIT 20

Filed Under Seal

EXHIBIT 21

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EXHIBIT 22

Filed Under Seal

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EXHIBIT 39

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EXHIBIT 40

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EXHIBIT 41

Filed Under Seal

EXHIBIT 42

Filed Under Seal

EXHIBIT 43

SOLVENCY CERTIFICATE

March 7, 2023

Pursuant to that certain Indenture, dated as of even date herewith (as the same may be amended, restated, supplemented and/or modified from time to time, the “Indenture”) by and among Invitae Corporation, a Delaware corporation (the “Company”), the Subsidiaries of the Company from time to time party thereto, U.S. Bank Trust Company, National Association as Trustee (in such capacity, the “Trustee”) and Collateral Agent, the undersigned hereby certifies to the Trustee and the Holders, solely in such undersigned’s capacity as Chief Financial Officer of the Company, and not individually (and without personal liability), as follows:

As of the date hereof, both before and after giving effect to the consummation of the Exchange Transaction and the other transactions contemplated in the Indenture and the other Notes Documents:

1. the value of the assets of the Company and its Subsidiaries, taken as a whole (both at fair value and present fair saleable value) is greater than the total amount of liabilities (including contingent and unliquidated liabilities) of the Company and its Subsidiaries, taken as a whole;
2. the Company and its Subsidiaries are able to pay all of its and its Subsidiaries liabilities as such liabilities mature;
3. the Company and its Subsidiaries, taken as a whole, do not have unreasonably small capital in relation to the Company’s and its Subsidiaries’ business as contemplated as of such date; and

For purposes of this Solvency Certificate, in computing the amount of contingent or unliquidated liabilities, such liabilities have been computed at the amount that, in light of all the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability. Capitalized terms used but not otherwise defined herein shall have the respective meanings assigned to them in the Indenture Agreement.

The undersigned is familiar with the business and financial position of the Company and its Subsidiaries (taken as a whole). In reaching the conclusions set forth in this Solvency Certificate, the undersigned has made such other investigations and inquiries as the undersigned has deemed appropriate, having taken into account the nature of the particular business anticipated to be conducted by the Company and its Subsidiaries (taken as a whole) after consummation of the transactions contemplated by the Indenture.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned has executed this Solvency Certificate in such undersigned's capacity as Chief Financial Officer of the Company as of the date first stated above.

INVITAE CORPORATION

DocuSigned by:
Roxi Wen
By: _____
37CB5F4AB4B54DA...
Name: Roxi Wen
Title: Chief Financial Officer

[Signature Page to Solvency Certificate]

EXHIBIT 44

Filed Under Seal

EXHIBIT 45

Filed Under Seal

EXHIBIT 46

In the Matter Of:

Live Realtime Auction

TRANSCRIPT OF PROCEEDING

April 17, 2024



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4.17.2024 AUCTION PROCEEDING
LIVE REALTIME AUCTION
HELD AT
KIRKLAND & ELLIS LLP
601 Lexington Avenue, 51st Floor
New York, New York

- - o 0 o - -

Invitae Corporation Chapter 11 Bankruptcy
in the U.S. Bankruptcy Court
for the District of New Jersey.

REPORTED BY: AMBRIA IANAZZI, RPR, CRR, CSR

1 A P P E A R A N C E S :

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10 olivia.acuna@kirkland.com, STEVE TOTH, JOSEPH
11 CASEY, ANTHONY MARESCO,
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AMY DONAHUE, DANIEL SAPOSNIK, CARLOTA MONTES,
HENRY MARTINEZ - VIA ZOOM

1 4.17.2024 AUCTION PROCEEDING

2 MR. PETRIE: Welcome,
3 everybody. My name is Francis
4 Petrie. I'm with Kirkland & Ellis,
5 proposed counsel for the debtors' in
6 the Invitae Corporation Chapter 11
7 Bankruptcy currently pending in the
8 U.S. Bankruptcy Court for the
9 District of New Jersey.

10 I'm here today with Ana
11 Schrank the CFO of Invitae
12 Corporation, my partners from
13 Kirkland & Ellis, Nicole Greenblatt,
14 Steve Toth, Joe Casey, and Spencer
15 Winters; FTI Consulting, the debtors
16 proposed financial adviser,
17 including Andrew Hinkelman, Andrew
18 Spirito, and the rest of their team,
19 and my colleagues from Moelis &
20 Company, Andrew Swift, Barak Klein,
21 Amy Chen, and the rest of their
22 team.

23 Today we're holding an
24 auction for all of the debtors'
25 assets to determine the successful

1 4.17.2024 AUCTION PROCEEDING
2 bidder, and backup bidder in
3 accordance with the auction
4 procedures set forth in the Bidding
5 Procedures Order entered on
6 February 16th, 2024 at Docket 57.

7 We do have a court reporter
8 here today. Ambria, thank you for
9 your time. So, this proceeding and
10 all bidding will be on the record.

11 To facilitate things for
12 our reporter, I ask that each
13 speaker identify themselves, and the
14 bidder they represent each time that
15 they speak, even if you have already
16 spoken, and then only one person
17 speaks at a time.

18 Each bidder should also
19 have one designated spokesperson to
20 avoid confusion regarding each
21 bidder's position. Multiple
22 spokespeople would confuse the
23 proceeding and probably delay the
24 auction.

25 So, we ask that at this

1 4.17.2024 AUCTION PROCEEDING

2 stage, the spokesperson for each
3 group identify themselves and spell
4 their name for the record. We'll
5 start over here.

6 MR. ASNANI: Sure. Anil --

7 MR. PETRIE: You might have
8 to press the bottom.

9 MR. ASNANI: Okay. Anil
10 Asnani with LabCorp. A-N-I-L, last
11 name, A-S-N-A-N-I.

12 MR. PETRIE: Okay. Thank
13 you.

14 MR. LYNN: Josh Lynn,
15 Warburg Pincus.

16 MR. PETRIE: Please say who
17 you are bidding on behalf of.

18 MR. LYNN: Oh, on behalf of
19 Helix.

20 MR. GOLDSTEIN: Michael
21 Goldstein, Goodwin Procter;
22 M-I-C-H-A-E-L, G-O-L-D-S-T-E-I-N, on
23 behalf of LetsGetChecked.

24 MR. PETRIE: Thank you.

25 MR. BLAUT: Ari Blaut;

1 4.17.2024 AUCTION PROCEEDING

2 A-R-I, B-L-A-U-T, from Sullivan &
3 Cromwell on behalf of Deerfield.

4 MR. PETRIE: Thank you.

5 And the bidders should be aware that
6 the members of --

7 Well, no, the financial
8 advisers and legal advisers to the
9 Committee are in attendance today as
10 well. If you'll be speaking, please
11 designate the spokesperson on your
12 behalf as well.

13 MR. DENMAN: Harrison
14 Denman, White & Case for the
15 Official Committee.

16 MR. PETRIE: Thank you.
17 That covers everybody.

18 So, the debtors' advisers
19 will be monitoring the auction
20 today, recognizing bids and other
21 comments. Per the auction rules,
22 which I'll run through right now,
23 the debtors have the right to cancel
24 or adjourn the auction at any time.

25 We've arranged for breakout

1 4.17.2024 AUCTION PROCEEDING
2 rooms for each of your groups as
3 needed to confer privately, but
4 before we move forward, we do want
5 to confirm that every party present
6 in this room first has not had
7 communications with any other
8 bidder, with the goal of either
9 controlling the price for the assets
10 being auctioned, or discouraging
11 other bidders' participation in this
12 auction, and that once the rounds of
13 bidding begin, each bidder's
14 qualified bid is a good-faith
15 bonafide offer, and that it intends
16 to consummate the proposed
17 transaction, if you are selected as
18 the successful bidder.

19 I want to remind you that
20 it is a federal crime to engage in
21 collusive bidding or to chill the
22 bidding.

23 By signing in on the
24 attendance sheet today, you
25 therefore agree that you have not

1 4.17.2024 AUCTION PROCEEDING
2 engaged in any collusion related to
3 this auction.

4 I'll now pause to give
5 everyone a moment to respond, if
6 what I said is not true.

7 Hearing nothing. We'll
8 continue.

9 Qualified bidders and their
10 agents will be allowed to
11 participate in the bidding, and the
12 debtors reserve the right to reject
13 any bid that is deemed inadequate,
14 or insufficient, or not in
15 conformity with the bidding
16 procedures, or contrary to the best
17 interest of the debtors, their
18 estates, or their creditors.

19 As set forth in the bidding
20 procedures, with the requisite
21 consents, and/or consultation of
22 certain parties, we reserve the
23 right to modify these auction rules
24 and the bidding procedures, or to
25 impose other terms and conditions

1 4.17.2024 AUCTION PROCEEDING

2 with respect to the auction, as we
3 determine may be in the best
4 interest of the sellers, their
5 estates, and their creditors.

6 The debtors have been in
7 discussions with the consultation
8 parties, as set forth in the bidding
9 procedures. We believe that all
10 parties here are qualified bidders,
11 for purposes of participation today,
12 but will note there are certain
13 contingencies that we plan to sort
14 out, prior to finally naming a
15 successful bidder.

16 The debtors reserve all
17 rights with regards to the naming of
18 qualified bidders in that regard.

19 The debtors also believe
20 that each of the bidders present has
21 at all times acted in good faith,
22 and negotiated at arm's length
23 during this process.

24 In accordance with the
25 Bidding Procedures Order, Deerfield

1 4.17.2024 AUCTION PROCEEDING
2 is not a consultation party for
3 purpose of analyzing other bids, due
4 to their participation in this
5 auction.

6 In advance of the auction,
7 the debtors have provided comments
8 on each qualified bidder's proposed
9 sale and related transaction
10 documents, including form APAs.
11 Each bidder may bid based on your
12 own bid documents, which the debtors
13 have determined are appropriate and
14 are acceptable transaction
15 documents.

16 And as bids get announced,
17 each qualified bidder will be
18 required to confirm on the record
19 that its bid is a good-faith
20 bonafide offer, and that you intend
21 to consummate the sale if selected
22 as the successful bid.

23 After the starting bid is
24 put on the record, any overbids must
25 be at least a 2 percent increase in

1 4.17.2024 AUCTION PROCEEDING
2 cash, cash equivalents, or other
3 consideration that the debtors
4 income, in consultation with the
5 committee, deem equivalent over the
6 previous bid.

7 Each successive overbid
8 shall exceed the then existing
9 overbid by an amount that is either
10 greater or equal to the minimum
11 overbid.

12 To remain eligible to
13 participate in each round of
14 bidding, each qualified bidder must
15 submit an overbid. If a qualified
16 bidder fails to submit an overbid in
17 a bidding round, that qualified
18 bidder will be disqualified from the
19 auction; however, the debtors may
20 waive that requirement in their
21 business judgment and in
22 consultation with the requisite
23 parties.

24 The auction will continue
25 until there is only one qualified

1 4.17.2024 AUCTION PROCEEDING
2 bid, or a combination of qualified
3 bids that the debtors determine in
4 their business judgment, in
5 consultation with the Committee, and
6 in a manner consistent with the
7 exercise of their fiduciary duties,
8 is the highest or otherwise best bid
9 to purchase the applicable assets;
10 and the debtors determine in their
11 business judgment, in consultation
12 with the consultation parties, that
13 further bidding is unlikely to
14 result in a different successful
15 bid, or successful bids that would
16 be reasonably acceptable to the
17 debtors, at which point, we will
18 close the auction.

19 The debtors will also
20 announce the backup bidder at the
21 conclusion of the auction, that is
22 the qualified bidder with the next
23 highest, or otherwise second best
24 qualified bid, and they're required
25 to serve in that capacity.

1 4.17.2024 AUCTION PROCEEDING

2 After the auction
3 concludes, within two business days,
4 the debtors will file a Notice with
5 the Court notifying parties in
6 interests of the successful bid.

7 If a successful bidder
8 fails to consummate its successful
9 bid, the debtors may select the
10 applicable backup bidder as the
11 successful bidder, and such backup
12 bidder shall be deemed a successful
13 bidder for all those purposes.

14 Please remember that the
15 hearing to consider approval of the
16 sale transaction is currently
17 scheduled to take place on May 6th,
18 at 10:00 a.m. prevailing Eastern
19 Time.

20 Are there any questions or
21 objections to the auction
22 procedures?

23 Hearing none, we're going
24 to go around and ask each party to
25 confirm that it understands the

1 4.17.2024 AUCTION PROCEEDING
2 terms of the auction as set forth in
3 the bidding procedures and as
4 announced today. Actually, if any
5 party just doesn't agree, speak up
6 now.

7 Cool.

8 Hearing nothing, we will
9 turn it over to Andrew Swift who
10 will announce what we believe to be
11 the starting bid.

12 MR. SWIFT: Sure.

13 Thank you. Can everyone
14 hear me?

15 Hi, Andrew Swift, I'm a
16 partner at Moelis & Company, a
17 proposed investment banker to the
18 debtors. We have a substantially
19 advanced APA with LabCorp, subject
20 to finalizing what I'll characterize
21 as a few remaining minor points to
22 the APA. LabCorp is the opening
23 qualified bidder with a bid of
24 \$183,000,000 in cash, and leaving
25 the estates with its accounts

1 4.17.2024 AUCTION PROCEEDING

2 receivable balance.

3 We would be happy to
4 discuss any purchase price
5 adjustments with the bidders off the
6 record, and we would note for the
7 record as well that despite this
8 post, we had a conditional higher
9 bid that we received, but the
10 conditionality was not sufficient at
11 this time to accept it as an opening
12 bid.

13 So, with that, we have
14 LabCorp's bid as an opening bidder,
15 and we ask the room if we have any
16 overbids at this time.

17 MR. GOLDSTEIN: I have a
18 question.

19 MR. SWIFT: Yes.

20 MR. GOLDSTEIN: Michael
21 Goldstein, Goodwin Procter on behalf
22 of LetsGetChecked. We request that
23 we have an opportunity to take a
24 break, and since we're just hearing
25 this for the first time right now,

1 4.17.2024 AUCTION PROCEEDING

2 to caucus, please.

3 MR. SWIFT: Of course. We
4 would propose a one-hour
5 adjournment, and then we could
6 reconvene at that time.

7 MR. GOLDSTEIN: A one-hour
8 adjournment?

9 MR. SWIFT: Yes.

10 MR. GOLDSTEIN: Thank you.

11 MR. PETRIE: We'll plan to
12 come back to this room at 2:15 and
13 then we'll plan to go back on the
14 record at that time.

15 MR. GOLDSTEIN: I'm sorry,
16 it's a little hard to hear. Could
17 you confirm or re-announce for us,
18 please, the purchase price number?

19 MR. SWIFT: Yeah, sorry.
20 \$183,000,000 in cash, with the
21 additional adjustment of leaving the
22 estate behind the accounts
23 receivable balance it projects at
24 the conclusion.

25 MR. PETRIE: Would you like

1 4.17.2024 AUCTION PROCEEDING

2 to confirm something, Anil?

3 MR. ASNANI: Yes, can you
4 hear me?

5 MR. PETRIE: We can.

6 MR. ASNANI: This is Anil
7 Asani with LabCorp. Just a
8 clarification, the bid value was
9 \$180 million? I thought I heard
10 \$183,000,000, so I want to clarify
11 that LabCorp --

12 MR. SWIFT: We'll confirm,
13 the bid with LabCorp is
14 \$180,000,000.

15 MR. PETRIE: We'll confirm
16 that.

17 MR. GOLDSTEIN: Can you
18 hear me?

19 Just to clarify, though,
20 the \$180 million to \$183 million
21 initial bid, that is straight cash
22 on top of the AR balance, or that
23 is --

24 Okay, so the AR balance
25 back, plus \$180 million to \$183

1 4.17.2024 AUCTION PROCEEDING

2 million of additional --

3 MR. PETRIE: Right.

4 MR. GOLDSTEIN: Okay.

5 That's the first question.

6 Second question, just for
7 the record, so a qualifying overbid
8 would be -- would have exactly how
9 much amount? It's 2 percent above
10 that --

11 MR. PETRIE: It's 2 percent
12 cash, cash equivalence or other
13 considerations.

14 MR. GOLDSTEIN: Above that
15 \$180,000,000 to \$183,000,000?

16 MR. SWIFT: So, the
17 \$180,000,000, plus the value of the
18 AR projected at the estate --

19 MR. GOLDSTEIN: So, that's
20 my question --

21 MR. SWIFT: So, it's
22 2 percent above that, so --
23 (Simultaneous speaking.)

24 MR. SWIFT: -- valuing the
25 AR with the bidders offering --

1 4.17.2024 AUCTION PROCEEDING

2 MR. GOLDSTEIN: Okay. And
3 is there anything else that we
4 should know about, in terms of
5 additional consideration, or
6 additional material terms that need
7 to be approved upon for the purpose
8 of the overqualified bid?

9 MR. SWIFT: No, not at this
10 time.

11 MR. GOLDSTEIN: Okay.
12 (Whereupon, a short recess was taken.)

13 MR. PETRIE: Thank you.
14 So, we'll go back on the record
15 right now.

16 It was announced at --
17 before we adjourned, what the
18 starting bid is, the LabCorp
19 \$180,000,000 plus AR. Would any
20 party like to submit an overbid at
21 this time?

22 MR. BLAUT: Ari Blaut from
23 Sullivan & Cromwell on behalf of
24 Deerfield. Our bid will consist of
25 \$227 million of debt, \$20 million of

1 4.17.2024 AUCTION PROCEEDING
2 cash. We'll leave it open, if
3 people prefer, who are going to
4 otherwise receive the cash that's
5 remaining in the estate; and if the
6 secureds choose to participate in
7 equity, we'll leave behind the AR.

8 MR. PETRIE: To confirm,
9 it's Deerfield assuming any cure
10 costs?

11 MR. BLAUT: Yeah. We're
12 going to act on, substantially the
13 same terms as the LetsGetChecked
14 APA.

15 MR. PETRIE: Thank you.
16 Would any other party like
17 to submit an overbid right now?

18 MR. GOLDSTEIN: Francis, if
19 I could make a statement?

20 MR. PETRIE: Yes.

21 MR. GOLDSTEIN: For the
22 record, Michael Goldstein, Goodwin
23 Procter on behalf of LetsGetChecked.
24 I just wanted to, on the record,
25 reaffirm our good-faith offer that

1 4.17.2024 AUCTION PROCEEDING
2 we submitted to the debtor, and that
3 we still have an intention to close
4 that. I just wanted to reaffirm
5 that on the record. Does that
6 offer -- does that bid exist, today
7 in this room.

8 As noted previously, from
9 the economic perspective, that is a
10 higher and better bid for the
11 estate, particularly given its
12 enterprise focus. But as also
13 noted, we understand the debtors
14 raised certain issues with respect
15 to that.

16 We have been working
17 feverously in realtime to respond
18 and address those in the context of
19 this process, which is complex and
20 moving very quickly. We're not
21 fully there, but we do need a bit
22 more time to -- and then technically
23 we can close them off.

24 As a qualified bidder, we
25 will continue to put ourselves in a

1 4.17.2024 AUCTION PROCEEDING

2 position to refine our bid, so we

3 can respond to further bidding.

4 Thank you.

5 MR. PETRIE: Thank you.

6 That message is well taken. You

7 will -- the debtors will not be

8 planning to disqualify anybody in

9 the room from further rounds of

10 bidding, even if you have not

11 submitted an overbid at this point.

12 (Simultaneous speaking.)

13 MR. PETRIE: Would any

14 other party like to submit a bid?

15 MR. DENMAN: Could we get a

16 few points of clarification on the

17 Deerfield bid?

18 This is Harrison Denman

19 from White & Case for the Official

20 Committee.

21 Could we get a -- is there

22 an APA accompanying the bid?

23 MR. GOLDSTEIN: Yes, the

24 APA is substantially the same APA as

25 I said, as that was previously

1 4.17.2024 AUCTION PROCEEDING

2 submitted by LetsGetChecked.

3 MR. DENMAN: Okay.

4 MR. GOLDSTEIN: With the
5 modifications that they have agreed
6 to with the debtors.

7 MR. DENMAN: Okay. Thank
8 you. And this is a 363 sale or is
9 this implemented by plan?

10 MR. GOLDSTEIN: Right now,
11 it is a 363 sale, but we are open to
12 implementing it as a plan, if that's
13 the best solution.

14 MR. PETRIE: Thank you.
15 Okay. With that, it's the debtors
16 view that Deerfield is the highest
17 and best bid at this point.

18 If no other party is
19 overbidding, we'll adjourn for a
20 brief period, another hour, and then
21 we can reconvene.

22 Thank you.

23 (Whereupon, a short recess was taken.)

24 MR. PETRIE: Francis Petrie
25 from Kirkland & Ellis on behalf of

1 4.17.2024 AUCTION PROCEEDING
2 the debtors. So, the latest round
3 of bidding left us with a leading
4 bid by Deerfield of \$227 million in
5 debt, \$20 million in cash, leaving
6 behind AR, the assumption of cure
7 costs on the terms set out on the
8 record at the last round of bidding.

9 Would any party like to
10 submit an overbid during this round?

11 MR. INTNER: This is
12 William Intner on behalf of LabCorp.
13 LabCorp would like to submit an
14 overbid. LabCorp bids \$206,080,000
15 on the terms of its previously
16 submitted APA, revised to provide
17 that the parties will agree to enter
18 into a mutually agreeable reverse
19 transition services agreement for
20 the purchaser to use transferred
21 employees for a 12-month period to
22 provide account receivables
23 collection services, other than
24 accounts receivable subject to
25 litigation, arbitration or similar

1 4.17.2024 AUCTION PROCEEDING

2 dispute mechanisms using the
3 seller's systems and contracts.

4 Sellers will be entitled to
5 100 percent of the collected
6 accounts receivable, and the
7 purchaser will be entitled to
8 receive a success fee equivalent to
9 the amount of collections in excess
10 of 90 percent of the non-disputed
11 outstanding accounts receivable.

12 MR. PETRIE: We've
13 confirmed with our financial
14 advisers, we do consider that to be
15 an overbid for purposes of this
16 round. Would any other party like
17 to submit a bid?

18 MR. GOLDSTEIN: Michael
19 Goldstein. Francis, could you
20 explain that? I would like to
21 get -- the bid was 206 --

22 MR. PETRIE: 206, yes --

23 MR. GOLDSTEIN: -- plus AR?

24 MR. PETRIE: Yes, plus AR
25 with its reverse TOA concept, and

1 4.17.2024 AUCTION PROCEEDING
2 what was it -- 206 in cash with --
3 MR. SWIFT: And I believe
4 that was -- this is Andrew Swift
5 investment banker to debtors. Just
6 to repeat the bid, I think it was a
7 clarifying question, in terms of
8 hearing it. The bid was 206 in
9 cash. The estate cash would be left
10 with the estate -- in a similar
11 fashion to other bids received thus
12 far to date, and in addition, there
13 were improvements on the terms of
14 the collection of the AR, which
15 would be left with the estate of
16 what would be enlarged in part,
17 prosecuted by a mutually acceptable
18 assumption of employees related to
19 those billings processes, such that
20 we were giving now incremental
21 credit to LabCorp for those AR
22 facility receivables.

23 I will -- we -- I don't
24 think we want to go on the record,
25 specifically with how we're valuing

1 4.17.2024 AUCTION PROCEEDING
2 that, but we're happy to have
3 off-the-record conversations around
4 those amounts, to the extent that
5 that's helpful to other bidders and
6 us.

7 MR. GOLDSTEIN: Yeah.
8 Michael Goldstein, Goodwin Procter.

9 Just for the record, we'll
10 just repeat what I said last time,
11 but we'll reaffirm --

12 MR. PETRIE: We reaffirm,
13 you will not be disqualified --
14 (Simultaneous speaking.)

15 MR. GOLDSTEIN: -- our
16 existing bid, and our intentions
17 with respect to that, and we would
18 be curious to have an off-the-record
19 understanding of the bid.

20 MR. SWIFT: Sure, we're
21 happy to have that.

22 MR. GOLDSTEIN: Thank you.

23 MR. BLAUT: This is Ari
24 Blaut from Sullivan & Cromwell on
25 behalf of Deerfield. We want to

1 4.17.2024 AUCTION PROCEEDING
2 reserve on whether this constitutes
3 an overbid until we get some more
4 detail on how the AR is being
5 evaluated during that --

6 (Simultaneous speaking.)

7 MR. PETRIE: Okay.

8 Understood.

9 Okay. So, based on that
10 hour, let's break -- let's plan to
11 be back in this room at 6:30, and
12 we'll have conversations in line
13 with the reservation of the rights.

14 MR. BLAUT: Thank you.

15 (Whereupon, a short recess was taken.)

16 MR. PETRIE: Okay.

17 Reopening the record.

18 This is Francis Petrie from
19 Kirkland & Ellis. When we were last
20 on the record, LabCorp was the
21 highest bid with the \$206,080,000
22 number with an adjustment to the AR.
23 We indicated on the record that that
24 was an overbid. We've been in
25 consultation with all parties since

1 4.17.2024 AUCTION PROCEEDING

2 then, and there remains an ongoing
3 dispute as to which bid is higher.

4 Each bidding party shall
5 reconfirm what is the -- currently
6 the highest bid, on the record, and
7 we'll start with LabCorp.

8 MR. INTNER: This is
9 William Intner on behalf of LabCorp.
10 Pursuant to the terms -- or, LabCorp
11 bids \$206,080,000 on the terms
12 previously submitted in the asset
13 purchase agreement revise to
14 provide that the parties agree to,
15 mutually agreeable under the
16 service -- reverse transition
17 services agreement for the purchaser
18 to use the transferred employees for
19 a 12-month-period to provide
20 accounts receivable, collection
21 services other than the account
22 receivable, subject to litigation,
23 arbitration, or similar dispute
24 mechanisms using the sellers systems
25 and contracts.

1 4.17.2024 AUCTION PROCEEDING

2 Sellers will be entitled to
3 100 percent of the collected
4 accounts receivable, and the
5 purchaser will be entitled to
6 receive success equivalent to the
7 amount out of collections in excess
8 of 90 percent of the non-disputed
9 outstanding accounts receivable.

10 MR. PETRIE: Thank you.

11 And we turn it over to Deerfield.

12 MR. BLAUT: Ari Blaut from
13 Sullivan & Cromwell on behalf of
14 Deerfield. We reaffirm our bid of
15 \$227 million of credit bid plus
16 \$20 million of cash. In addition,
17 we'll leave behind the accounts
18 receivable, the cure costs, and of
19 course, we will take the transfer
20 tax on substantially the terms of
21 the LetsGetChecked in of the APA.

22 MR. PETRIE: Okay. With
23 that, we're offering the UCC to make
24 a comment on the record, if they
25 choose to make an exception.

1 4.17.2024 AUCTION PROCEEDING

2 MR. DENMAN: No comment.

3 MR. PETRIE: So, with that
4 we plan to consult internally with
5 our board, and we plan to reconvene
6 on Friday. And with that, this
7 auction is adjourned.

8 MS. GREENBLATT: Just to be
9 clear for the debtors, our intention
10 is to reconvene at 9:00 a.m. Friday
11 morning, likely via Zoom. We'll get
12 the detailed Zoom information out to
13 all the parties. Thank you.

14

15 -o0o-

16 (Whereupon, the AUCTION was concluded at
17 11:58 p.m.)

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C E R T I F I C A T E

I, AMBRIA IANAZZI, a Registered Professional Reporter, Certified Realtime Reporter, New York Association Certified Reporter, New York Realtime Certified Reporter, Certified Shorthand Reporter and Notary Public in New York do hereby certify:

That the AUCTION PROCEEDING is hereinbefore set forth, and that such transcript is a verbatim record of the proceeding.

I further certify that I am not related to any of the parties to this action by blood or marriage; and that I am in no way interested in the outcome of this matter.

In witness whereof, I have hereunto set my hand this 22nd day of April, 2024.

Ambria Ianazzi

AMBRIA IANAZZI, RPR, CRR, CSR

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In the Matter Of:

Invitae Corporation Chapter 11 Bankruptcy

AUCTION

April 24, 2024



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4/24/2024 AUCTION PROCEEDING

LIVE REALTIME AUCTION

HELD VIRTUALLY

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Invitae Corporation Chapter 11 Bankruptcy
In the U.S. Bankruptcy Court
For the District of New Jersey.

DATE: April 24, 2024
TIME: 10:00 a.m.
REPORTER: Hope Agosto, PCR
Court Reporter - Notary Public

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P R O C E E D I N G S

MS. GREENBLATT: This is
Nicole Greenblatt from Kirkland &
Ellis on behalf of the debtors.
We are back on the record in the
auction for the Invitae debtors
jointly administered under Case
Number 24-11362 pending in the
District of New Jersey.

We last adjourned the auction
last Wednesday where the last bid
on the record was from LabCorp of
approximately 206 million dollars.
There were some questions over
whether that qualified as an
overbid to the prior Deerfield
bid.

We adjourned the auction to
Friday to allow parties to
continue to work on their bids and
to understand what the benefit of
help from our financial advisors
at Moelis, the various credits and

1 analysis that was driving the
2 value of the different bids based
3 on the different forms of
4 consideration that they consisted
5 of.

6 Those conversations were
7 productive, and then the parties
8 asked for an additional
9 adjournment given the Passover
10 holidays over the past two days.

11 We are now back on the record
12 today. The time is 10:07. And I
13 understand that there is a party
14 who would like to clarify what its
15 current bid is.

16 So if there's a representative
17 on hand from LabCorp who would
18 like to put something on the
19 record, I will turn it over to you
20 at this time.

21 MS. BRADY: Thank you, Nicole.

22 Erin Brady from Hogan &
23 Lovells on behalf of LabCorp.

24 So I guess just to clarify the
25 record, our position is that the

1 206 million dollar cash component
2 bid that we put in at the auction
3 on Wednesday isn't LabCorp's
4 current bid. Our understanding,
5 and I'd ask you to clarify, is
6 that Deerfield's current bid or
7 last bid on the record is the
8 highest bid at this point. And if
9 that's the case, then that would
10 mean that LabCorp's 206 million
11 dollar bid that was put on the
12 record -- when I say that, I mean
13 cash -- which was made after
14 Deerfield's bid would have been
15 rejected and therefore couldn't
16 have been a qualified bid in the
17 first place.

18 So if it was rejected as a
19 qualified bid, then our view is
20 that it's not LabCorp's current
21 bid and that LabCorp's current bid
22 would be 180 million dollars,
23 which was the opening bid.

24 So I think at this point it
25 makes sense just to reserve our

1 rights on that issue, and then to
2 the extent it would become
3 relevant, which I hope it won't,
4 LabCorp would object to being
5 named as the backup bidder at the
6 206 million dollar bid.

7 MS. GREENBLATT: Understood.
8 Sorry, Nicole Greenblatt on behalf
9 of the debtors.

10 Understood that that's your
11 position. We did not make a final
12 determination on behalf of the
13 debtors as to whether or not that
14 was an overbid, and we would also
15 reserve rights to so declare that
16 as a backup bid. But all rights
17 are reserved for purposes of
18 today.

19 MS. BRADY: Thank you.
20 And then at this point, are
21 you guys open for new bids?

22 Should we be making a bid?

23 MS. GREENBLATT: Yes, please,
24 if you have a bid to put on the
25 record, you can certainly go

1 first.

2 MS. BRADY: Yes, certainly.

3 So LabCorp is prepared to
4 overbid the current Deerfield bid,
5 and that overbid is going to be on
6 the terms of the APA that was
7 dated April 16th, 2024 that
8 LabCorp provided to the debtors
9 immediately prior to the auction
10 beginning last Wednesday, with a
11 few modifications.

12 So the cash component of that
13 bid is going to be raised to 239
14 million dollars. LabCorp and the
15 debtors will enter into a reverse
16 TSA on the terms that LabCorp read
17 into the record at the auction
18 last Wednesday on the 17th in
19 conjunction with the 206 million
20 dollar bid that may or may not be
21 in dispute.

22 LabCorp will acquire the
23 offensive litigation and any
24 proceeds therefrom that is the
25 subject of Section 6.17 of the APA

1 but will not share with the
2 debtors any proceeds received as a
3 result of purchasing that
4 litigation. That's a
5 clarification -- a modification
6 since the last time we were here.

7 LabCorp will clarify in
8 Section 6.3 of the APA the target
9 cash incentive opportunities
10 offered by LabCorp to the
11 transferred employees, will take
12 into consideration the value of
13 retention bonuses under the
14 debtors' 2024 equivalent retention
15 program, but excluding transition
16 bonuses and other retention
17 bonuses.

18 LabCorp will require the
19 debtors to engage a third party
20 consultant approved by LabCorp to
21 advise on and assist with the IT
22 plan set forth on Section 6.18 of
23 the APA and will reimburse the
24 debtors for the reasonable
25 documented incremental cost to the

1 sellers of that exercise,
2 including the cost of the third
3 party consultant in an amount not
4 to exceed 4 million dollars.

5 And then finally, LabCorp will
6 consider in good faith the use of
7 alternative tax efficient
8 mechanisms for the transfer of
9 acquired assets held by the
10 non-debtors, including considering
11 a royalty-free irrevocable license
12 to the intellectual property held
13 by Orbicule BVBA.

14 So I think all of the terms I
15 just read are -- and I guess read
16 into the record are consistent
17 with the discussions that we have
18 been having with the debtors and
19 are in the process of being
20 documented in a revised APA.

21 And I think with that, that
22 concludes the terms of the bid.

23 Anil, can I just have you
24 confirm that I got that right?

25 MR. ASNANI: Yes, this is Anil

1 Asnani with LabCorp and I'm
2 confirming that you got that
3 right. Thank you.

4 MR. BLAUT: And a quick
5 clarification, how does the bid
6 treat --

7 MS. GREENBLATT: Say your
8 name.

9 MR. BLAUT: Ari Blaut from
10 Sullivan & Cromwell on behalf of
11 Deerfield.

12 Just a clarification on the
13 treatment of the transfer taxes
14 and the admin claims and the cure
15 costs?

16 MS. BRADY: I'll -- I'm going
17 to bounce that to William Intner.

18 MR. INTNER: The bid treats
19 cure costs in -- this is William
20 Intner from Hogan & Lovells on
21 behalf of LabCorp. The bid treats
22 -- assumes cure costs for
23 contracts that will be assumed.

24 And Ari, I'm not sure I know
25 specifically what you're asking on

1 the transfer tax point.

2 MR. BLAUT: I think there was
3 a cost on the taxes, on the
4 transfer of the taxes -- the
5 transfer taxes here that was in
6 the model that people had been
7 knocking around and who was going
8 to be responsible for paying
9 those.

10 MR. INTNER: I would refer to
11 the APA previously provided to the
12 debtors on the treatment of
13 transfer taxes.

14 MS. GREENBLATT: It's Nicole
15 Greenblatt on behalf of the
16 debtors.

17 Steve Toth, if you're on the
18 call, could you clarify the
19 treatment of transfer taxes in the
20 LabCorp APA as it stands today?

21 MR. TOTH: I'm pretty sure the
22 purchaser is paying the transfer
23 taxes.

24 MR. BLAUT: Thank you.

25 MS. GREENBLATT: This is

1 Nicole Greenblatt again, on behalf
2 of debtors.

3 Would anyone else like to make
4 a statement at this time, or does
5 anyone require any additional time
6 to confer with their clients as to
7 whether they would like to make an
8 overbid?

9 MR. BLAUT: Could we -- It's
10 Ari Blaut from Sullivan &
11 Cromwell.

12 Could we have a 15-minute
13 adjournment and reconvene at 10:30
14 so we could discuss quickly with
15 our client?

16 MS. GREENBLATT: Yes. Any
17 objection by anyone on the phone
18 to taking a 15-minute adjournment?

19 (No response.)

20 Hearing none, we will
21 reconvene at 10:30 on this line.
22 Everyone should just kind of close
23 their screens and not try to
24 rejoin on because that will take
25 15 minutes.

1 Thank you.

2 * * *

3 (Whereupon, a brief recess was
4 held at this time.)

5 * * *

6 MS. GREENBLATT: Nicole
7 Greenblatt on behalf of the
8 debtors. I have 10:30 by my
9 watch, so we are back on the
10 record.

11 I'll turn it over to Mr. Blaut
12 from Sullivan & Cromwell who asked
13 for the adjournment.

14 MR. BLAUT: Ari Blaut from
15 Sullivan & Cromwell on behalf of
16 Deerfield.

17 Deerfield will not be
18 submitting a revised bid.

19 MS. GREENBLATT: Thank you,
20 Mr. Blaut.

21 Would anyone else like to put
22 anything on the record at this
23 time in response to the last bid
24 we got from LabCorp?

25 (No response.)

1 Okay. Hearing nothing, we, on
2 behalf of the debtors, are going
3 to adjourn until 1 o'clock today
4 so we can consult with our board
5 as to whether we believe the last
6 LabCorp bid at 239 with the
7 changes announced on the record
8 is, in fact, the successful
9 overbid or not.

10 So we will reconvene at 1
11 o'clock to make that
12 determination. If we have made
13 that determination, we might
14 otherwise file a notice on the
15 docket and not reconvene everyone.
16 So we will notify the parties on
17 this chain one way or the other
18 before 1 o'clock today.

19 Thank you all very much. We
20 very much appreciate everyone's
21 hard work. I know it's been a
22 long haul, so thank you very much
23 for everyone's efforts, and we are
24 adjourned.

25 Thank you.

1 * * *

2 (Whereupon, a recess was held
3 until 1:00 p.m. EST.)

4 * * *

5 MR. PETRIE: Good afternoon,
6 everyone. This is Francis Petrie
7 of Kirkland on behalf of debtors.

8 The last time we were on the
9 record we confirmed that LabCorp's
10 bid for a headline price of 239
11 million qualifies as an overbid.
12 In the debtor's assessment, this
13 is currently the highest and best
14 bid.

15 At this time, would any party
16 like to submit a topping bid?

17 (No response.)

18 Hearing nothing, we'll
19 proceed.

20 For the record, can somebody
21 from LabCorp or Hogan please
22 confirm the 239 million purchase
23 price?

24 MR. ASNANI: This is Anil
25 Asnani with LabCorp. I'm

1 confirming the 239 million dollar
2 purchase price.

3 MR. PETRIE: Thank you, Anil.

4 So with that, we confirm that
5 we will now designate LabCorp's
6 bid for 239 million as the
7 successful bid.

8 I'd like to confirm the
9 understanding of all parties that
10 the bidding process is complete
11 once we close the auction and that
12 there was no collusion in this
13 auction.

14 The hearing to approve the
15 results of today's auction will
16 take place on May 6th at 10:00
17 a.m. in the Bankruptcy Court for
18 the District of New Jersey.

19 With that, we have a
20 successful bid and we will close
21 the record and this auction.

22 Thank you all for attending.

23 The auction is now closed.

24 (Auction concluded at
25 1:04 p.m.)


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C E R T I F I C A T I O N

* * *

I, Hope Agosto, Professional Court
Reporter and Notary Public for the Commonwealth
of Pennsylvania, do hereby certify the
foregoing to be a true and accurate transcript
of my original stenographic notes taken at the
time and place hereinbefore set forth.



Hope Agosto
Court Reporter
Notary Public

(The foregoing certification of this
transcript does not apply to any reproduction
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<hr/> <p style="text-align: center;">1</p> <hr/> <p>10:07 9:12 10:30 17:13,21 18:8 15 17:25 15-minute 17:12,18 16th 12:7 17th 12:18 180 10:22</p> <hr/> <p style="text-align: center;">2</p> <hr/> <p>2024 12:7 13:14 206 8:15 10:1,10 11:6 12:19 239 12:13 24-11362 8:10</p> <hr/> <p style="text-align: center;">4</p> <hr/> <p>4 14:4</p> <hr/> <p style="text-align: center;">6</p> <hr/> <p>6.17 12:25 6.18 13:22 6.3 13:8</p> <hr/> <p style="text-align: center;">A</p> <hr/> <p>acquire 12:22 acquired 14:9 additional 9:8 17:5 adjourned 8:12,20 adjournment 9:9 17:13,18 18:13 admin 15:14 administered 8:9 advise 13:21 advisors 8:24 alternative 14:7 amount 14:3 analysis 9:1 Anil 14:23,25</p>	<p>APA 12:6,25 13:8,23 14:20 16:11,20 approved 13:20 approximately 8:15 April 12:7 Ari 15:9,24 17:10 18:14 Asnani 14:25 15:1 assets 14:9 assist 13:21 assumed 15:23 assumes 15:22 auction 8:8,12,20 10:2 12:9,17</p> <hr/> <p style="text-align: center;">B</p> <hr/> <p>back 8:7 9:11 18:9 backup 11:5,16 based 9:2 beginning 12:10 behalf 8:6 9:23 11:8,12 15:10,21 16:15 17:1 18:7,15 benefit 8:23 bid 8:13,19 9:15 10:2,4,6,7,8,11,14, 16,19,21,23 11:6,16,22,24 12:4,13,20 14:22 15:5,18,21 18:18,23 bidder 11:5 bids 8:22 9:2 11:21 Blaut 15:4,9 16:2,24 17:9,10 18:11, 14,20 bonuses 13:13,16,17 bounce 15:17 Brady 9:21,22 11:19 12:2 15:16 BVBA 14:13</p> <hr/> <p style="text-align: center;">C</p> <hr/> <p>call 16:18 case 8:9 10:9 cash 10:1,13 12:12 13:9 claims 15:14 clarification 13:5 15:5,12 clarify 9:14,24 10:5 13:7 16:18 client 17:15</p>	<p>clients 17:6 close 17:22 component 10:1 12:12 concludes 14:22 confer 17:6 confirm 14:24 confirming 15:2 conjunction 12:19 consideration 9:4 13:12 consisted 9:4 consistent 14:16 consultant 13:20 14:3 continue 8:22 contracts 15:23 conversations 9:6 cost 13:25 14:2 16:3 costs 15:15,19,22 credits 8:25 Cromwell 15:10 17:11 18:12,15 cure 15:14,19,22 current 9:15 10:4,6,20,21 12:4</p> <hr/> <p style="text-align: center;">D</p> <hr/> <p>dated 12:7 days 9:10 debtors 8:6,8 11:9,13 12:8,15 13:2, 19,24 14:18 16:12,16 17:2 18:8 debtors' 13:14 declare 11:15 Deerfield 8:18 12:4 15:11 18:16,17 Deerfield's 10:6,14 determination 11:12 discuss 17:14 discussions 14:17 dispute 12:21 District 8:11 documented 13:25 14:20 dollar 10:1,11 11:6 12:20 dollars 8:15 10:22 12:14 14:4</p>
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EXHIBIT 47

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) February 28, 2023

Invitae Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36847
(Commission
File Number)

27-1701898
(IRS Employer
Identification No.)

1400 16th Street
San Francisco, California 94103
(Address of principal executive offices, including Zip Code)

(415) 374-7782
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Exchange Agreements

On February 28, 2023, Invitae Corporation (the “Company”) announced it has entered into separate, privately negotiated purchase and exchange agreements (collectively, the “Exchange Agreements”) with certain holders of the Company’s currently outstanding 2.00% Convertible Senior Notes due 2024 (the “Old Notes”). Pursuant to the Exchange Agreements, the Company will (a) exchange \$305,727,000 aggregate principal amount of the Old Notes for \$275,257,000 aggregate principal amount of its new 4.5% Series A Convertible Senior Secured Notes due 2028 (the “Series A New Notes”) and 14,219,859 shares (the “New Shares”) of the Company’s common stock, \$0.0001 par value per share (the “Common Stock”), and (b) issue and sell \$30,000,000 aggregate principal amount of its new 4.5% Series B Convertible Senior Secured Notes due 2028 (the “Series B New Notes”) and, together with the Series A New Notes, the “New Notes”) for cash (collectively, the “Transactions”). The New Notes and New Shares will be issued in private placements exempt from registration in reliance on Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The New Notes will be issued pursuant to an indenture (the “New Notes Indenture”). The Transactions are subject to customary closing conditions and are expected to close on or about March 7, 2023.

The New Notes Indenture

The Notes will accrue interest at a rate of 4.5% per annum, payable quarterly in arrears on March 15, June 15, September 15 and December 15 of each year, beginning on June 15, 2023. The Notes will mature on March 15, 2028, unless earlier repurchased, redeemed or converted.

Based on the initial conversion price of \$2.5800, the New Notes will be convertible into 118,316,667 shares of Common Stock, subject to the potential issuance of additional shares in the event of optional redemptions or Major Transactions (discussed below).

At any time prior to the 60th day prior to the maturity date of the New Notes, the Company will have the option to redeem all or any portion of the principal amount of the New Notes for cash equal to the principal amount of the New Notes to be redeemed, subject to certain conditions specified in the New Notes Indenture. Upon redemption of any New Notes, the Company will (i) issue Warrants (as defined below) covering the same number of shares of Common Stock underlying, and at an exercise price equal to the conversion price of, the redeemed New Notes, unless the aggregate principal amount of New Notes outstanding represents less than 10% of the aggregate principal amount of New Notes initially issued and certain other conditions are satisfied, and (ii) make a make-whole payment as determined pursuant to the New Notes Indenture, together with accrued and unpaid interest through the redemption date. In addition, in certain circumstances, the Company may be required to issue additional shares of Common Stock for any New Notes converted in connection with a notice of optional redemption. The Company will not be able to effect any optional redemption during a delisting event or unless all conversion shares and warrant shares are freely tradable and unless certain other conditions specified in the New Notes Indenture are satisfied.

The New Notes will be convertible at any time at the holder's option, provided that the holder is prohibited from converting New Notes into shares of Common Stock if, upon such conversion, the converting holder (together with certain affiliates and "group" members) would beneficially own more than 4.9% of the total number of shares of Common Stock then issued and outstanding (the "Beneficial Ownership Cap"). In addition, prior to such time that the Company obtains the stockholder approval for the issuance of shares of Common Stock in excess of the limitations imposed by the NYSE rules (the "NYSE Cap"), the holder is prohibited from converting New Notes into shares of Common Stock in excess of such NYSE Cap, and the Company would instead be required to settle any conversion in cash if the Company is not able to obtain the stockholder approval within the grace period specified in the New Notes Indenture.

If the Company undergoes a "Major Transaction" (as defined in the New Notes Indenture), holders may require the Company to repurchase for cash all or part of their New Notes at a purchase price equal to 100% of the principal amount of the New Notes to be repurchased, plus (i) accrued and unpaid interest to, but excluding, the repurchase date and (ii) the make-whole amount as determined pursuant to the New Notes Indenture. In addition, at the election of the holders of the New Notes, the Company may be required to issue additional shares of Common Stock for any New Notes converted in connection with a Major Transaction.

The New Notes will be guaranteed by the Company's material subsidiaries and secured by (i) a security interest in substantially all of the assets of the Company and its domestic and material subsidiaries and (ii) a pledge of the equity interests of the Company's direct and indirect subsidiaries, subject to certain customary exceptions. The New Notes Indenture contains certain specified events of default, the occurrence of which would entitle the holders of the New Notes to demand repayment of all outstanding principal and accrued interest on the New Notes, together with a make-whole payment as determined pursuant to the New Notes Indenture. Such events of default include, among others, failure to make any payment under the New Notes when due, failure to observe or perform certain covenants under the New Notes or the other transaction documents related thereto (subject in certain cases to specified cure periods), the failure of the Company to be able to pay debts as they come due, the commencement of bankruptcy or insolvency proceedings against the Company, a material judgment levied against the Company and any event of default by the Company under other indebtedness.

The New Notes Indenture will also include a number of affirmative covenants, including covenants regarding compliance with applicable laws and regulations, reporting, maintenance of property, payment of taxes and maintenance of insurance, among other covenants. The New Notes Indenture will also include a number of restrictive covenants, including restrictions on business combinations, incurrence of additional liens or indebtedness, prepayments of other indebtedness, dispositions, investments, and transactions with affiliates, in each case subject to certain exceptions. The Company will also be required to comply with certain financial maintenance covenants, including a minimum revenue covenant and, starting with the fiscal quarter ending March 31, 2025, a minimum liquidity covenant. The Company is also restricted from paying dividends or making other distributions or payments on its capital stock, subject to certain exceptions.

Warrants

The New Notes Indenture will also provide for the issuance of warrants to purchase Common Stock (the "Warrants") in connection with (i) redemption of the New Notes or (ii) acceleration of the New Notes following the occurrence of an Event of Default as a result of a failure by the Company to settle any conversion in cash. Any Warrants issued will cover the

same number of shares of Common Stock underlying, and will be exercisable upon the payment of the exercise price of, the prepaid New Notes. If issued, the Warrants will be exercisable on a cash or cashless (net exercise) basis, and will be subject to a beneficial ownership cap and a NYSE Cap (until such time that stockholder approval is obtained), as well as certain other customary anti-dilution adjustments upon the occurrence of certain events such as stock splits, subdivisions, reclassifications or combinations of Common Stock. Upon the consummation of a "Major Transaction" (as defined in the Warrants), holders of the Warrants may elect to (i) have their Warrants redeemed by the Company for an amount equal to the Black-Scholes value of such Warrant, in cash or, if applicable, in the form of the consideration paid to the Company's stockholders in a Major Transaction, or (ii) have such Warrants be assumed by the successor to the Company in a Major Transaction, if applicable. Holders of the Warrants are also entitled to participate in any dividends or distributions to holders of Common Stock at the time such dividends or distributions are paid to such stockholders.

If issued, the Warrants and the shares of Common Stock issuable upon their exercise will be issued in a private placement pursuant to Section 4(a)(2) of the Securities Act in transactions not involving a public offering (or, in the case of the issuance of shares of Common Stock pursuant to certain non-cash exercises of the Warrants, pursuant to Section 3(a)(9) under the Securities Act as an exchange with existing security holders).

Registration Rights Agreement

Pursuant to the Exchange Agreements, the Company has also agreed to prepare and file with the Securities and Exchange Commission (the "SEC") a Registration Statement on Form S-3, or such other form as required to effect a registration of the Common Stock issued or issuable upon conversion of or pursuant to the Series B New Notes and certain of the Warrants (the "Registrable Securities"), covering the resale of the Registrable Securities and such indeterminate number of additional shares of Common Stock as may become issuable upon conversion of or otherwise pursuant to the Series B New Notes and Warrants to prevent dilution resulting from certain corporate actions. Such Registration Statement must be filed within 10 business days following the closing of the Transactions.

The foregoing description of the Exchange Agreements, the New Notes Indenture, the Warrants and the Registration Rights Agreement does not purport to be complete and is qualified in its entirety by reference to the Form of Purchase and Exchange Agreement, Form of Registration Rights Agreement, Form of New Notes Indenture and Form of Warrant, a copy of each of which is filed herewith as Exhibits 10.1, 10.2, 4.1 and 4.2, respectively, and incorporated herein by reference.

Item 1.02 Termination of a Material Definitive Agreement

With respect to that certain Credit Agreement and Guaranty, dated as of October 2, 2020, by and among the Company, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP as the Administrative Agent (such Credit Agreement, as amended to date, the "Secured Credit Facility"), on February 28, 2023, the Company prepaid \$85.0 million in principal, representing the entire amount outstanding under the Secured Credit Facility, together with accrued interest on such prepaid principal of \$1,882,018.06 and a prepayment fee of \$5.1 million as required under the terms of the Secured Credit Facility.

The foregoing discussion, to the extent involving the Secured Credit Facility, is not intended to be complete and is qualified in its entirety by reference to the original Secured Credit Facility as well as the first and second amendments thereto, which are Exhibits 10.4, 10.5 and 10.6, respectively, to this Current Report on Form 8-K, and incorporated herein by reference.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information set forth under Item 1.01 of this Current Report on Form 8-K regarding the New Notes and the New Notes Indenture is incorporated herein by reference.

Item 3.02. Unregistered Sales of Equity Securities.

The information set forth under Item 1.01 of this Current Report on Form 8-K regarding the issuance and sale of the New Notes and Warrants is incorporated herein by reference.

Item 8.01. Other Events.

Supplemental Risk Factors

In light of the Transactions described in Item 1.01 of this Current Report on Form 8-K assuming closing of the Transactions, the Company is supplementing the risk factors previously disclosed in Part I., Item 1A. of its Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the Securities and Exchange Commission on February 28, 2023, to include the following risk factor under the heading “Risk Factors – Risks related to our indebtedness”:

The terms of our convertible senior secured notes will require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

Assuming a closing of the transactions contemplated by the Exchange Agreements, we will issue \$305.3 million aggregate principal amount of our 4.5% convertible senior secured notes due 2028, or the convertible senior secured notes. The convertible senior secured notes will be secured by a first priority lien on substantially all of our and our subsidiaries’ assets (including our intellectual property) and will be guaranteed by our subsidiaries, in each case, excluding certain excluded assets and immaterial subsidiaries.

The indenture governing our convertible senior secured notes will restrict our ability, among other restrictions, pursue certain dispositions, mergers or acquisitions, encumber our intellectual property, incur indebtedness or liens, pay dividends or make other payments in respect of our capital stock, make investments and engage in certain other business transactions. In addition, the indenture contains financial covenants that will require us to maintain revenue in the prior four quarters of not less than \$250.0 million and, starting with the quarter ending March 31, 2025, a minimum liquidity of at least 15% of the amount of our secured indebtedness then outstanding. If we fail to comply with these or any of the other covenants under the indenture and are unable to obtain a waiver or amendment, the holders of the convertible senior secured notes may, among other things, declare all of the convertible senior secured notes due and payable and exercise rights with respect to collateral securing those notes, each of which could significantly harm our business, financial condition and prospects and could cause the price of our common stock to decline.

If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

If our stockholders do not approve the conversion of the convertible senior secured notes, we may not have the cash necessary to settle such notes in cash upon conversion.

Our convertible senior secured notes will be convertible at any time at the option of the holders thereof, provided that the holders are prohibited from converting such notes into shares of common stock in excess of the limitations imposed by the rules of the New York Stock Exchange prior to such time that we obtain stockholder approval for the issuance of such excess shares of common stock. In the absence of stockholder approval, we will be required, after the grace period specified under the indenture with respect to the convertible senior secured notes, to settle any conversion of the excess shares in cash at the then current fair market value, if the holders elect to convert. If we are unable to obtain the requisite stockholder approval and holders convert the convertible senior secured notes, we may not have sufficient cash to satisfy our obligations to the converting holders.

We have a large amount of debt, servicing our debt requires a significant amount of cash, we may not have sufficient cash flow from our business to service our debt, and we may need to refinance all or a significant portion of our debt.

Assuming the closing of the transactions contemplated by the Exchange Agreements, as of such closing, we will have outstanding \$44.3 million aggregate principal amount our existing convertible senior notes due 2024, or the existing 2024 notes, \$1,150.0 million aggregate principal amount of our existing convertible senior notes due 2028, or the existing 2028 notes, and \$305.3 million aggregate principal amount of our new convertible senior secured notes due 2028. We refer to the existing 2024 notes and the existing 2028 notes as the existing convertible notes.

Our substantial leverage could have significant negative consequences for our future operations, including:

- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financial for working capital, acquisitions, research and development expenditures, and general corporate purposes;
- requiring the dedication of a substantial portion of our cash flow or our existing cash to service our indebtedness, thereby reducing the amount of our cash available for other purposes;

- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; or
- placing us at a possible competitive disadvantage compared to less leveraged competitors and competitors that have better access to capital resources.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt, including paying off the principal when due, and to make necessary capital expenditures. The respective conversion prices of our existing convertible notes are significantly higher than the prevailing market prices for our common stock, and our stock price would have to increase significantly in order for holders to convert such notes prior to maturity. If we are unable to generate cash flow necessary to service or repay our debt at maturity, we may be required to adopt one or more alternatives, including, but not limited to, selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time, and the terms of any such refinancing may be less favorable to us than the terms of our current indebtedness. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to repurchase our existing convertible notes or convertible senior secured notes upon a fundamental change or major transaction, as applicable, and the indenture governing our convertible senior secured notes contains, and our future debt may contain, limitations on our ability to pay cash to repurchase our existing convertible notes and other debt.

Holders of our existing convertible notes have the right to require us to repurchase all or any portion of their notes upon the occurrence of a fundamental change, as defined in the respective indentures governing our existing convertible notes, at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. The repurchase price for our 2028 convertible notes will also include unpaid interest on such notes to the maturity date. Similarly, holders of our convertible senior secured notes will have the right to require us to repurchase all or any portion of their notes upon the occurrence of a major transaction, as defined in the indenture governing our convertible senior secured notes, for an amount equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest and a make whole amount as set forth in such indenture. The indenture governing our convertible senior secured notes will limit our ability to pay cash to repurchase our existing convertible notes, and we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of notes surrendered for repurchase. In addition, our ability to repurchase our existing convertible notes or our convertible senior secured notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the respective indentures governing the notes would constitute a default under the relevant indentures. A default under an indenture or the occurrence of the fundamental change or major transaction itself could also lead to a default under the indentures governing our other convertible notes or any agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and to repay or repurchase our convertible notes.

In the event the conditional conversion feature of our existing 2024 notes is triggered, holders of such notes will be entitled to convert the notes at any time during specified periods at their option. If one or more holders elect to convert their notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which could result in a material reduction of our net working capital.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the closing of the transaction, including the timing of and conditions to closing; the anticipated use of proceeds from the transaction; and any expected benefits from the transaction. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: risks related to whether the Company will be able to satisfy the conditions required to close the transaction; the fact that the Company's management will have broad discretion in the use of the proceeds from the transaction and risks and uncertainties related to that use of proceeds; the potential impact of market and other general economic conditions; the ability of the Company to successfully execute its strategic business realignment plan and achieve the intended benefits thereof on the expected timeframe or at all; the Company's failure to manage growth effectively; the Company's failure to fully realize the anticipated benefits of the transaction; and the other risks set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 and in the Company's subsequent filings with the Commission. These forward-looking statements speak only as of the date hereof, and the Company disclaims any obligation to update these forward-looking statements.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
4.1	Form of New Notes Indenture
4.2	Form of Warrant
10.1	Form of Purchase and Exchange Agreement
10.2	Form of Registration Rights Agreement

Exhibit No.Description

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- 10.4 [Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent \(incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on October 5, 2020\).](#)
- 10.5 [Amendment No. 1, dated as of April 3, 2021, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent, to Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent \(incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on April 5, 2021\).](#)
- 10.6 [Amendment No. 2, dated as of September 20, 2021, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent, to Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 9, 2021\).](#)
- 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

Black-Scholes Value

Remaining Term	Number of calendar days from date of consummation or occurrence of the Major Transaction or Event of Default until the last date on which this Warrant may be exercised.
Interest Rate	A risk-free interest equal to 4.55% for a period equal to the Remaining Term.
Cost to Borrow	Zero
Volatility	60%
Stock Price	<p><u>Major Transaction:</u></p> <p>The greatest of (1) the per share closing (last sale) price of the Common Shares on the New York Stock Exchange, or, if that is not the principal trading market for the Common Shares, such principal market on which the Common Shares are traded or listed (the "Closing Market Price") on the Trading Day immediately preceding the date on which the Major Transaction is consummated or otherwise occurs, (2) the first Closing Market Price following the first public announcement of the Major Transaction, and (3) the Closing Market Price as of the date immediately preceding the first public announcement of the Major Transaction.</p> <p><u>Event of Default:</u></p> <p>The greatest of (1) the per share closing (last sale) price of the Common Shares on the New York Stock Exchange, or, if that is not the principal trading market for the Common Shares, such principal market on which the Common Shares are traded or listed (the "Closing Market Price") on the Trading Day immediately preceding the date on which the Event of Default occurs, (2) the first Closing Market Price following the first public announcement of the Event of Default (as applicable), and (3) the Closing Market Price as of the date immediately preceding the first public announcement of the Event of Default (as applicable).</p>

Invitae Corporation

February 28, 2023

FORM OF PURCHASE AND EXCHANGE AGREEMENT

1. Introduction. Invitae Corporation, a Delaware corporation (the “Company”), proposes (i) to exchange (the “Exchange Transaction”) \$[•] aggregate principal amount of the Company’s 2.00% Convertible Senior Notes due 2024, CUSIP 46185 LAB9 (the “Old Notes”) held by certain existing holders of the Old Notes listed on the signature pages hereto (the “Investors”) for \$[•] aggregate principal amount of the Company’s 4.50% Series A Convertible Senior Secured Notes due 2028 (the “Series A New Notes”) and such number of shares equal to (x) \$[•], [including \$[•] in respect of accrued and unpaid interest on the Old Notes], divided by (y) the closing price of the Common Stock on February 28, 2023 (the “Investor New Shares”) of the Company’s common stock, \$0.0001 par value per share (the “Common Stock”), such Series A New Notes and Investor New Shares to be newly issued by the Company on the Closing Date (as defined below), (ii) substantially concurrently with the consummation of the Exchange Transaction, issue and sell \$[•] aggregate principal amount of the Company’s 4.50% Series B Convertible Senior Secured Notes due 2028 (the “Series B New Notes”) and, together with the Series A New Notes, the “New Notes”) to certain of the Investors as set forth on the signature pages hereto (such Investors, in such capacity, the “Subscribing Investors”) on the Closing Date (the “Subscription Transaction”) and (iii) substantially concurrently with the execution of this Agreement (as defined below), enter into agreements (the “Other Agreements”) with certain other investors (the “Other Investors”) to exchange (the “Additional Exchange Transactions”) \$[•] aggregate principal amount of Old Notes held by such Other Investors for \$[•] aggregate principal amount of Series A Notes and such number of shares of Common Stock equal to (x) \$[•] divided by (y) the closing price of the Common Stock on February 28, 2023 (the “Other New Shares”) and, with the Investor New Shares, the “New Shares”), and issue and sell \$[•] aggregate principal amount of Series B New Notes, all of which to be newly issued by the Company on the Closing Date (the “Additional Subscription Transaction”).

The Exchange Transaction, the Subscription Transaction, the Additional Exchange Transaction and the Additional Subscription Transaction are collectively referred to herein as the “Transactions” and, subject to the terms and conditions thereof, will collectively result in (A) the Company exchanging \$305,727,000 of Old Notes for \$275,257,000 of New Series A Notes and such number of shares equal to (x) \$30,572,700 divided by (y) the closing price of the Common Stock on February 28, 2023 and (B) the Company issuing and selling \$30,000,000 of Series B New Notes.

The Old Notes were issued pursuant to that certain Indenture, dated as of September 10, 2019, between the Company and U.S. Bank Trust Company, National Association (as successor to U.S. Bank National Association), as trustee (in such capacity, the “Old Notes Trustee”). The New Notes will be issued pursuant to an Indenture (the “New Notes Indenture”), to be dated as of the Closing Date, among the Company, as issuer, the guarantors party thereto (the “Guarantors”) and U.S. Bank Trust Company, National Association, as trustee (in such capacity, the “New Notes Trustee”) and collateral agent (in such capacity, the “Collateral Agent”), substantially in the form set forth in Exhibit B hereto.

The New Notes and the guarantees of the New Notes (the "**Guarantees**") will be secured by a first-priority lien, subject to Liens permitted by Section 4.27 of the New Notes Indenture ("**Permitted Liens**"), pursuant to the terms of the New Notes Indenture and a Security Agreement (the "**Security Agreement**"), to be dated as of the Closing Date, between the Company and the Collateral Agent, substantially in the form set forth in Exhibit C hereto, on substantially all of the tangible and intangible assets of the Company and the Guarantors, now owned or hereafter acquired by the Company and any Guarantor, subject to certain exceptions described in the New Notes Indenture and the Collateral Documents.

The New Notes will be convertible into shares of Common Stock (the shares of Common Stock underlying the New Notes, including any Additional Conversion Shares, the "**Conversion Shares**"), cash or a combination thereof pursuant to the terms and conditions set forth in the New Notes Indenture. Upon certain redemptions of the New Notes, the holders thereof will be issued Warrants (the "**Warrants**") to purchase shares of Common Stock (such shares and any other shares of Common Stock issuable upon exercise of, or otherwise pursuant to, the Warrants, the "**Warrant Shares**"), as provided in the New Notes Indenture. The New Notes, the Guarantees, the New Shares, the Conversion Shares, the Warrants and the Warrant Shares are referred to collectively herein as the "**Securities**" and, for the avoidance of doubt, include any and all New Notes, Guarantees, New Shares, Conversion Shares, Warrants and Warrant Shares, as applicable, issued or issuable to Other Investors in connection with the Other Agreements.

The Securities are being offered to the Investors and the Other Investors pursuant to this Agreement (as defined below) and the Other Agreements, as applicable, only to institutional "accredited investors" within the meaning of Rule 501 of Regulation D under the Securities Act of 1933, as amended, including the rules and regulations promulgated thereunder (the "**Securities Act**"), that are also qualified institutional buyers within the meaning of Rule 144A under the Securities Act and "Institutional Accounts" as defined in the Financial Industry Regulatory Authority ("FINRA") Rule 4512(c), pursuant to exemptions from registration under the Securities Act provided by Section 4(a)(2) thereof and/or Rule 506 of Regulation D thereunder.

Notwithstanding anything herein to the contrary, the parties hereto agree and acknowledge that the Perceptive Facility (as defined below), if not terminated prior to the date hereof, shall be terminated prior to the effectiveness of the New Notes Indenture and the Security Agreement and related security documents.

2. Exchange Transaction and Additional Exchange Transactions. Each Investor agrees, severally and not jointly, for itself and on behalf of any beneficial owners of Old Notes being exchanged for whom such Investor holds contractual and investment authority, upon the terms and subject to the conditions set forth in this Purchase and Exchange Agreement (the "**Agreement**"), to exchange the aggregate principal amount of Old Notes (such aggregate principal amount of Old Notes, the "**Exchanged Old Notes**") held by such Investor and set forth on Exhibit A-1 hereto on the Closing Date, for (a) the aggregate principal amount of Series A New Notes set forth on Exhibit A-1 hereto across from such Investor's name, such amount being equal to approximately 90% of the aggregate principal amount of such Investor's Exchanged Old Notes and (b) the number of New Shares set forth on Exhibit A-1 hereto across from such Investor's name (collectively, the "**Exchange Transaction New Securities**"), and the Company agrees to deliver the applicable amounts of such Investor's Exchange Transaction New Securities to such Investor in exchange for such Exchanged Old Notes tendered by such Investor in the Exchange Transaction on the Closing Date.

The Company has separately agreed with each of the Other Investors, pursuant to conditions set forth in the Other Agreements, to exchange the aggregate principal amount of Old Notes (such aggregate principal amount of Old Notes, the "**Additionally Exchanged Old Notes**") held by such Other Investors for (a) an aggregate principal amount of Series A New Notes being equal to approximately 90% of the aggregate principal amount of such Other Investors' Additionally Exchanged Old Notes and (b) the Other New Shares (collectively, the "**Additional Exchange Transactions New Securities**"), and the Company has agreed to deliver the applicable amounts of such Other Investors' Additional Exchange Transactions New Securities to the applicable Other Investors in exchange for such Additionally Exchanged Old Notes tendered by such Other Investors in the Additional Exchange Transactions on the Closing Date. The Exchange Transaction New Securities and the Additional Exchange Transactions New Securities are referred to collectively herein as the "**Exchange Consideration**."

3. **Subscription for New Notes.** Each Subscribing Investor agrees, severally and not jointly, upon the terms and subject to the conditions set forth in this Agreement, to purchase from the Company for the applicable cash consideration set forth next to such Subscribing Investor's name on Exhibit A-2 hereto (the "**Cash Consideration**"), the applicable aggregate principal amounts of Series B New Notes similarly set forth next to such Subscribing Investor's name on Exhibit A-2 hereto (the "**Subscription Transaction New Notes**" and together with the Exchange Transaction New Securities and the Additional Exchange Transactions New Securities, the "**New Securities**"), which aggregate principal amount of Subscription Transaction New Notes shall equal the Cash Consideration payable by such Subscribing Investor, and the Company agrees to issue and sell to each such Subscribing Investor the applicable amount of Subscription Transaction New Notes purchased by such Subscribing Investor in the Subscription Transaction upon receipt by the Company of the applicable amounts of Cash Consideration on the Closing Date.

4. **Settlement of the Exchange Transaction and the Subscription Transaction.**

(a) The settlement of the Transactions (the "**Settlement**") shall be made remotely via the exchange of documents and signatures at 10:00 A.M., New York City time, on March 7, 2023, or at such other place, time or date as the Investors, on the one hand, and the Company, on the other hand, may agree upon, such time and date of Settlement being herein referred to as the "**Closing Date**."

(b) On the Closing Date, subject to satisfaction of the conditions precedent specified in this Agreement, substantially contemporaneously, (i) each Investor shall cause the Exchanged Old Notes held by such Investor to be delivered, by book entry transfer through the facilities of The Depository Trust Company ("**DTC**"), to the Old Notes Trustee, for the account/benefit of the Company for cancellation (and such cancellation shall promptly be effected), and pursuant to the instructions included in the Exchange Procedures set forth on Exhibit A-3 hereto, and (ii) the Company shall execute, and cause the New Notes Trustee to execute and authenticate and cause to be delivered to, or for the benefit of, each Investor, the applicable amount of Exchange Transaction New Securities due to such Investor upon consummation of the Exchange Transaction as specified herein.

(c) On the Closing Date, subject to the satisfaction of the conditions precedent specified in this Agreement, (i) each of the Subscribing Investors shall cause the applicable amounts of Cash Consideration payable by such Subscribing Investor to be delivered to the Company by wire transfer in immediately available funds to the account specified by the Company on Exhibit A-4 hereto, and, upon receipt of the Cash Consideration, and (ii) the Company shall execute, and cause the New Notes Trustee to execute and authenticate and cause to be delivered to, or for the benefit of each of the Subscribing Investors, the applicable amount of Subscription Transaction New Notes due to such Subscribing Investor upon consummation of the Subscription Transaction as specified herein.

(d) The New Securities to be delivered to, or for the benefit of, each Investor on the Closing Date shall be delivered by causing the New Notes Trustee and the Transfer Agent to electronically transmit the applicable amounts of New Securities due to such Investor by crediting the account of the Investor's prime broker with DTC through its Deposit/Withdrawal at Custodian system, as specified by such Investor.

(e) [On or prior to the Closing Date, subject to the satisfaction of the conditions precedent specified in this Agreement, (i) each Investor shall execute and deliver each Transaction Document to which it is a party, and (ii) the Company and each Guarantor shall execute and deliver, and cause the Trustee and the Collateral Agent to execute and deliver, each Transaction Document to which the Company, a Guarantor, the Trustee and/or the Collateral Agent is a party.]

5. Definitions. Wherever used in this Agreement or related exhibits, unless the context otherwise requires, the following terms have the meanings assigned to such terms in this Section 5. Capitalized terms used but not defined herein have the meanings assigned to such terms in the New Notes Indenture.

“2022 10-K” means the Company's annual report on form 10-K for the year ended December 31, 2022, in a form substantially identical to the version provided to the Investors prior to the date of this Agreement.

“Approved Stock Plan” means any stock incentive plan that has been duly adopted by the Board of Directors and approved by the stockholders of the Company, pursuant to which the Company's securities may be issued solely to employees, officers, directors and consultants for services provided to the Company.

“Board of Directors” means the Company's board of directors.

“Federal Reserve Board” means the Board of Governors of the Federal Reserve System or any entity succeeding to any of its principal functions.

“Government Program” means Medicare, Medicaid or other federal or state health program (as defined in 42 U.S.C. § 1320a-7b(f)) or other similar federal, state or local reimbursement program for which the federal, state or local government pays, in whole or in part, directly or indirectly, for the provision of healthcare services or goods.

“Margin Stock” means “margin stock” as such term is defined in Regulation T, U or X of the Federal Reserve Board.

“Non-SEC Document Qualified Representations” means the representations and warranties made by the Company other than the SEC Document Qualified Representations.

“Options” means any rights, warrants or options to subscribe for or purchase shares of Common Stock or Convertible Securities.

“Outside Counsel” means, in respect of any Investor, such Investor’s outside counsel as may be designated from time to time by such Investor for purposes hereof and the other Transaction Documents (including, to the extent applicable, receiving notices and communications hereunder and under the other Transaction Documents).

“SEC Document Qualified Representations” means the representations and warranties made by the Company in Sections 6(f), 6(j), 6(k), 6(l), 6(o), 6(r), 6(u), 6(w) and 6(gg).

“Solvent” means, with respect to any Person, as of any date of determination, that, as of such date, (a) the value of the assets of such Person and its Subsidiaries, taken as a whole (both at fair value and present fair saleable value) is greater than the total amount of liabilities (including contingent and unliquidated liabilities) of such Person and its Subsidiaries, taken as a whole, (b) such Person and its Subsidiaries are able to pay all liabilities of such Person and its Subsidiaries as such liabilities mature and (c) such Person and its Subsidiaries, taken as a whole, do not have unreasonably small capital in relation to such Person’s and its Subsidiaries’ business as contemplated as of such date. In computing the amount of contingent or unliquidated liabilities at any time, such liabilities shall be computed at the amount that, in light of all the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability.

“Transaction Documents” means this Agreement, the Other Agreements, the Notes, the New Note Indenture, the Note Guarantees, the Collateral Documents, each Compliance Certificate, the Perfection Certificate, the Solvency Certificate, [the Registration Rights Agreement,] the Intercompany Subordination Agreement and all other documents, agreements and instruments delivered in connection with any of the foregoing or the Transactions, in each case, as amended, restated, supplemented or otherwise modified from time to time.

“United States” and **“U.S.”** each means the United States of America.

“USA Patriot Act” means the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, P.L. 107-56, as amended from time to time.

6. Representations and Warranties of the Company and Guarantors. Each of the Guarantors represent and warrant to each Investor that, except, solely for purposes of the SEC Document Qualified Representations, as described in the SEC Documents filed with or furnished to the Commission after December 31, 2021 and at least five (5) Business Days prior to the date hereof or the 2022 10-K (but excluding any cautionary or predictive disclosures that do not expressly relate to specific prior occurrences at the Company or any Guarantor set forth under the headings “Risk Factors” or disclosure of risks set forth in any “forward-looking statements” disclaimer, or disclosures in any other statements that are similarly cautionary or predictive in nature and provided that the Non-SEC Document Qualified Representations shall not be qualified by any disclosures in the SEC Documents and that no disclosure included in the 2022 10-K that was not included in the form thereof provided to the Investors prior to the date of this Agreement shall qualify any of the SEC Document Qualified Representations, as of the date hereof:

(a) No Default. No Default or Event of Default will exist immediately following the Closing Date or will result from the consummation of the Transactions.

(b) Solvency. On the Closing Date (both before and after giving effect to the Transactions), the Company and each of the Guarantors (i) is Solvent and (ii) has not taken action, and no action has been taken by a third party, for the winding up, dissolution or liquidation or similar executory or judicial proceeding in respect of the Company or any of the Guarantors, or for the appointment of a liquidator, custodian, receiver, trustee, administrator or other similar officer for the Company or any of the Guarantors or any or all of their assets or revenues.

(c) Enforceability. This Agreement and each Other Agreement constitutes, and each other Transaction Document will constitute, when executed and delivered by the Company, and duly authorized, executed and delivered by the applicable counterparties thereto (and specifically with respect to the New Notes and the Warrants, when issued and delivered in the manner provided for in the New Notes Indenture), a legal, valid and binding obligation of the Company and each of the Guarantors, as applicable, enforceable against the Company and each of the Guarantors in accordance with its terms (and with respect to the New Notes, entitled to the benefits of the New Notes Indenture), except as the enforcement hereof or thereof may be limited by insolvency, bankruptcy, reorganization, moratorium or other similar Applicable Laws affecting creditors rights generally or general principles of equity, [and except with respect to the indemnification provisions of the Registration Rights Agreement, which may be limited by applicable securities laws and public policy thereunder].

(d) Existence, Qualification and Power. The Company and each of the Guarantors is validly existing as a corporation, limited liability company, limited partnership or other form, as applicable, and is in good standing (to the extent such concept is applicable in the relevant jurisdictions) under the laws of the jurisdiction of its incorporation, organization or formation, as applicable. The Company and each Guarantor (a) has full power and authority (and all Authorizations) to (i) own its properties, conduct its business, own its assets and operate its facilities and (ii) to (A) with respect to the Company, issue the New Shares, the New Notes, the Conversion Shares, the Warrants and the Warrant Shares in accordance with the Transaction Documents, (B) enter into, execute, deliver and perform its obligations under, the Transaction Documents, including, with respect to the Company, the issuance of the New Shares, the New Notes and the Warrants

and the reservation for issuance of the Conversion Warrant, and (b) is duly qualified as a foreign corporation, limited liability company or limited partnership, as applicable, and licensed and in good standing, under the laws of each jurisdiction where its ownership, lease or operation of property or the conduct of its business requires such qualification or license, except, in each case of this clause (b), where the failure to be so qualified, licensed or in good standing would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(e) Collateral Documents, Financing Statements and Collateral. After giving effect to the repayment and termination of that certain Credit Agreement and Guaranty, dated as of October 2, 2020, by and among the Company, as the borrower, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto, and Perceptive Credit Holdings III, LP, as the Administrative Agent (as amended prior to the Closing Date, the “**Perceptive Facility**”) and the discharge of all associated Obligations under the Perceptive Facility:

(i) Upon execution and delivery, the Security Agreement and each of the Intellectual Property Security Agreements will be effective to grant a legal, valid and enforceable security interest in all of the grantor’s right, title and interest in the Collateral;

(ii) Upon due and timely filing and/or recording of the financing statements and Intellectual Property Security Agreements with respect to the Collateral described in the Security Agreement and the Intellectual Property Security Agreements (the “**Personal Property Collateral**”), the security interests granted thereby will constitute valid, perfected first-priority liens and security interests in the Personal Property Collateral, to the extent such security interests can be perfected by the filing and/or recording, as applicable, of financing statements and Intellectual Property Security Agreements for the benefit of the Trustee and the Collateral Agent for the benefit of the holders of the Securities, and such security interests will be enforceable in accordance with the terms contained therein against all creditors of any grantor or mortgagor and subject only to Permitted Liens;

(iii) Upon execution and delivery by the parties thereto of the Control Agreements as required by Section 4.12 of the New Notes Indenture, the security interests in deposit accounts granted pursuant to the Security Agreement will constitute valid, perfected first-priority liens and security interests for the benefit of the Trustee and the Collateral for the benefit of the holders of the Securities, enforceable in accordance with the terms contained therein against all creditors of any grantor and subject only to Permitted Liens; and

(iv) The Company and its Subsidiaries collectively own, have rights in or have the power and authority to collaterally assign rights in the Collateral, free and clear of any Liens other than the Permitted Liens.

(f) Litigation. No Proceeding is pending or known to be pending by the Guarantors, threatened by, any Governmental Authority (a) to which the Company or any Guarantor is a party, (b) that purports to affect or pertain to the Transaction Documents, the Transactions or any other transactions contemplated hereby or thereby or (c) that has as the subject thereof any assets owned by the Company or any of its Subsidiaries, in each case, that would, if adversely determined, reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. No injunction, writ, temporary restraining order or any order of any nature has been issued by any court or other Governmental Authority purporting to enjoin or restrain the execution, delivery or performance of this Agreement or any other Transaction Document or directing that the Transactions or any other transactions provided for herein or therein not be consummated as herein or therein provided.

(g) Corporate Authorization; Conflicts. This Agreement and each of the Other Agreements has been, and as of the Closing Date, each of the other Transaction Documents shall be, duly authorized, executed and delivered by the Company and the Guarantors, as applicable. The execution, delivery and performance of the Transaction Documents by the Company and the Guarantors, as applicable, and the consummation of the Transactions, including the issuance of the New Shares, the New Notes and any Warrants and any issuance of Conversion Shares and Warrant Shares, and the granting of any Liens or other security interests to be granted by the Company or the Guarantors pursuant to the New Notes Indenture and the Collateral Documents, as applicable, will not (a) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any Lien (other than any Lien created or imposed pursuant to the Collateral Documents) upon any assets of the Company or the Guarantors pursuant to any agreement, document or instrument to which the Company or any Guarantor is a party or by which the Company or any Guarantor is bound or to which any of the assets or property of the Company or any Guarantor is subject, except, with respect to this clause (a), as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, (b) result in any violation, or conflict with any, of the Organizational Documents of the Company or any Guarantor, (c) result in the violation of any Applicable Law (including, without limitation, the rules and regulations of the Principal Market) except, with respect to this clause (c), as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, or (d) result in the violation of any judgment, order, rule, corporate integrity agreement, regulation, determination or decree of any Governmental Authority binding upon the Company or any Guarantor.

(h) Governmental Authorizations. Except in each case, as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect: (a) the Company and each Guarantor holds, and is operating in compliance with, all franchises, grants, Authorizations, licenses, permits, easements, consents, certificates, enforcement discretion policies and orders of any Governmental Authority (collectively, "Required Authorizations") required for the conduct of its business, and all Required Authorizations are valid and in full force and effect, and (b) no Authorization of, or registration, notice or filing with, any Governmental Authority is required for (i) the execution, delivery and performance of any of the Transaction Documents, and (ii) the consummation by the Company or any of the Guarantors of the Transactions or any other transactions contemplated by the Transaction Documents, except (A) for such as have already been

obtained or made prior to the Closing Date that are required in connection with the perfection of any security interest in or exercise of remedies in respect of the Collateral, (C) pursuant to applicable federal and state securities laws, rules and regulations that are expressly contemplated by Section 13 or 15(d) of the Exchange Act [and by the Registration Rights Agreement], or (D) for filings expressly contemplated or required by the Transaction Documents.

(i) Ownership of Real Estate and Personal Property. As of the Closing Date, the Real Estate constitutes all of the Real Estate owned or leased by the Company and each of its Subsidiaries. The Company and each Subsidiary has good and marketable title to all of their assets and property free and clear of all Liens, except with respect to Permitted Liens. The property, including real property, held under lease by the Company and each of the Guarantors is held under valid, subsisting and enforceable leases with only such exceptions with respect to any particular lease as do not interfere, individually or in the aggregate, in any material respect with the conduct of the business of the Company and the Guarantors.

(j) Intellectual Property. The Company and each of its Subsidiaries owns, licenses or otherwise has the right to use all Material IP that is necessary for the operation of its businesses as currently conducted (provided that the parties agree that the foregoing should not be interpreted as a non-infringement representation). All of the registered Intellectual Property, or applications for such registration, are maintained in good standing (other than intentional abandonment of trademark and patent applications that are no longer deemed by Company to be material to its business as currently conducted) and, to the Company's knowledge, are valid and enforceable. As of the Closing Date, (a) the use by the Company and its Subsidiaries of its Intellectual Property does not infringe any Intellectual Property owned by any other Person in a manner that would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, (b) the Company and each of its Subsidiaries have not transferred ownership of, entered any agreement, or granted any exclusive license (other than the Intellectual Property License Agreement executed in connection with the IDT Purchase Agreement) with respect to, any Material IP, (c) the Company has not entered any agreement or license to Intellectual Property that affects the exclusive right of the Company or any of the Guarantors to develop, license, market or sell their services or products as currently conducted or proposed to be conducted as of the Closing Date (other than (i) the Intellectual Property License Agreement executed in connection with the IDT Purchase Agreement and (ii) any license agreement for Material IP entered into in connection with a court order, settlement, compromise or other resolution of a litigation, arbitration or other dispute) and (d) other than as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, no other Person has contested any right, title or interest of the Company or any of its Subsidiaries in, or relating to, any Intellectual Property owned by the Company or any Subsidiary. As of the Closing Date, (x) there are no pending (or, to the knowledge of the Company, threatened in writing) Proceedings affecting the Company or any of its Subsidiaries with respect to its Intellectual Property, (y) there is no judgment or order regarding any such claim described in subsection (x) that has been rendered by any competent Governmental Authority with respect to any of the Company's or its Subsidiaries' Intellectual Property, and (z) there is no settlement agreement or similar

agreement that has been entered into by the Company and its Subsidiaries, or to any such infringement of any Intellectual Property owned by any other Person or that would limit, cancel or question the validity of the Company's or any of its Subsidiaries' rights in any Intellectual Property owned by the Company or a Subsidiary, in each case of (x)-(z) other than as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(k) Taxes. All U.S. federal, state and local income and franchise and other material Tax returns required to be filed by the Company and each Guarantor (taken into account applicable extensions) have been filed with the appropriate Governmental Authorities, and all Taxes reflected therein or otherwise due and payable (taken into account applicable extensions) have been paid prior to the date on which any material Liability may be added thereto for non-payment thereof except for those contested in good faith by appropriate proceedings diligently conducted and for which adequate reserves are maintained on the books of the Company or the Guarantor (as applicable) in accordance with GAAP or to the extent that failure to do so would not result in a Material Adverse Effect.

(l) Compliance with Laws. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, the Company and each of the Guarantors is in compliance with all Applicable Laws (including applicable Health Care Laws) and Authorizations.

(m) SEC Documents. The Company has filed, through the Commission's Electronic Data Gathering, Analysis, and Retrieval system (or successor thereto) ("EDGAR"), all of the SEC Documents within the time frames prescribed by the Commission for the filing of such SEC Documents such that each filing was timely filed with the Commission. As of their respective dates, each of the SEC Documents filed on or prior to the date hereof complied, and as of the date of its filing with the Commission, the 2022 10-K will comply, in all material respects with the requirements of the Securities Act and/or the Exchange Act (as applicable) and the rules and regulations of the Commission promulgated thereunder applicable to the SEC Documents (including the 2022 10-K). Since the filing of the SEC Documents, no event has occurred that would require an amendment or supplement to any of the SEC Documents and as to which such an amendment or a supplement has not been filed and made publicly available on EDGAR on or prior to the date this representation is made. The Company has not received any written comments from the Commission staff that have not been resolved to the satisfaction of the Commission staff.

(n) Financial Statements; Financial Condition. As of their respective dates, the consolidated financial statements of the Company and its Subsidiaries included in the SEC Documents complied, and as of the date thereof the consolidated financial statements of the Company and its Subsidiaries included in the 2022 10-K will comply, as to form in all material respects with applicable accounting requirements and the published rules and regulations of the Commission (including Regulation S-X) with respect thereto. Such financial statements (including the financial statements to be included in the 2022 10-K) have been prepared in accordance with GAAP (subject, in the case of unaudited quarterly

financial statements, to normal year-end adjustments (including adjustments for contingencies), and fairly present in all material respects the consolidated financial position of the Company and its Subsidiaries as of the dates thereof and the consolidated results of their operations, cash flows and changes in stockholders equity for the periods specified. There are no material off-balance sheet arrangements or any relationships with unconsolidated entities or other Persons that (a) may have a material current or, to the Company's or any of its Subsidiaries' knowledge, future effect on the Company's or any of its Subsidiaries' financial condition, results of operations, liquidity, capital expenditures, capital resources or significant components of revenue or expenses or (b) that are required to be disclosed by the Company in the SEC Documents that have not been so disclosed in the SEC Documents (or in the case of the 2022 10-K, that are required to be disclosed by the Company in an annual report on Form 10-K for the year ended December 31, 2022 that are not disclosed in the 2022 10-K). The accounting firm that expressed its opinion with respect to the consolidated financial statements included in the Company's most recently filed annual report on Form 10-K and in the 2022 10-K, and reviewed the consolidated financial statements included in the Company's most recently filed quarterly report on Form 10-Q, was independent of the Company pursuant to the standards set forth in Rule 2-01 of Regulation S-X promulgated by the Commission and as required by the applicable rules and guidance of the Public Company Accounting Oversight Board (United States), and such firm was otherwise qualified to render such opinion under Applicable Law and the rules and regulations of the Commission. There are no material disagreements of any kind presently existing, or reasonably anticipated by the Company to arise, between the Company and such accounting firm. Neither the Company nor any of its Subsidiaries is required to file or will be required to file any agreement, note, lease, mortgage, deed or other instrument entered into prior to the date this representation is made and to which the Company or any of its Subsidiaries is a party or by which the Company or any of its Subsidiaries is bound that has not been previously filed as an exhibit (including by way of incorporation by reference) to the Company's reports filed with the Commission under the Exchange Act. Set forth on Section 6(n) of the disclosure schedule delivered to the Investors concurrently herewith (the "**Disclosure Schedule**") is a list of all of the Company's outstanding Indebtedness as of the date hereof. Other than (i) the outstanding Indebtedness set forth on Section 6(n) of the Disclosure Schedule, (ii) the liabilities assumed or created pursuant to this Agreement and the other Transaction Documents, (iii) liabilities accrued for in the latest balance sheet included in the Company's 2022 10-K (the date of such balance sheet, the "**Latest Balance Sheet Date**") and (iv) liabilities incurred in the ordinary course of business consistent with past practice since the Latest Balance Sheet Date, the Company and its Subsidiaries do not have any off balance sheet obligations or other contingent obligations. Since the Latest Balance Sheet Date, (i) there has been no Material Adverse Effect or any event or circumstance that would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect and (ii) neither the Company nor any of its Subsidiaries has sold any material assets, or entered into any material transactions, outside of the ordinary course of business, and (iii) the Company has not declared, paid or made any dividends or other distributions to holders of its Stock.

(o) Accounting Controls. The Company and its Subsidiaries maintain internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that comply with the requirements of the Exchange Act and have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset and liability accountability; (iii) access to assets or incurrence of liability is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets and liabilities is compared with the existing assets and liabilities at reasonable intervals and appropriate action is taken with respect to any differences. The Company and its Subsidiaries have (i) timely filed and made publicly available on EDGAR all certifications, statements and documents required by (1) Rule 13a-14 or Rule 15d-14 under the Exchange Act. The Company and its Subsidiaries maintain disclosure controls and procedures required by Rule 13a-15 or Rule 15d-15 under the Exchange Act; such controls and procedures are effective to ensure that the information required to be disclosed by the Company and its Subsidiaries in the reports that they file with or submit to the Commission (A) is recorded, processed, summarized and reported accurately within the time periods specified in the SEC's rules and forms and (ii) is accumulated and communicated to the Company's (and, to the extent applicable, its Subsidiaries') management, including its or their principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. The Company's internal control over financial reporting required by Rule 13a-15 or Rule 15d-15 under the Exchange Act; such internal control over financial reporting as of December 31, 2022 was effective and did not contain any material weaknesses.

(p) Subsidiaries. (a) Each of the Subsidiaries of the Company and all joint ventures and other partnerships in which the Company or any of its Subsidiaries own Stock are set forth in Section 6(p)(a) of the Disclosure Schedule (with such Section 6(p)(a) of the Disclosure Schedule also identifying each of the Immaterial Subsidiaries and Excluded Subsidiaries as of the Closing Date), (b) the Stock of the Company and each of its Subsidiaries is duly authorized, validly issued, fully paid and non-assessable (to the extent applicable thereto), (c) none of the Stock of the Company or any of its Subsidiaries constitutes Margin Stock, (d) the SEC Documents correctly set forth the ownership interest of each of the Company's Subsidiaries in each of the Subsidiaries identified therein, (e) each of the Foreign Subsidiaries is an Immaterial Subsidiary and (f) no Subsidiary designated as an Immaterial Subsidiary owns, holds or exclusively licenses any Material IP. All outstanding Stock of each Subsidiary of the Company is owned beneficially and of record by the Company or a Subsidiary of the Company, and after giving effect to the repayment and termination of the Perceptive Facility, free and clear of all Liens other than (i) those held by the Investors and (ii) Permitted Liens. All such securities were issued in compliance with all applicable state and federal laws concerning the issuance of securities. There are no pre-emptive rights, rights to purchase, options, warrants or other similar rights, or other understandings to which the Company or any of its Subsidiaries is a party with respect to (including any restriction on) the issuance, voting, disposition or pledge of any Stock of any such Person.

(q) Shares of Stock. All of the issued and outstanding shares of the Company and its Subsidiaries are duly authorized and duly and validly issued, fully paid and non-assessable, have been issued in compliance with all federal and state and foreign securities laws and were not issued in violation of or subject to any preemptive rights or other rights to subscribe for or purchase securities that have not been waived in writing. Upon the issuance in accordance with the terms of the Transaction Documents (including the New Notes and any Warrants), the holders of the New Notes and the Warrants will be entitled to the rights set forth in the New Notes and the Warrants, respectively. The New Shares have been duly authorized and, when issued pursuant to this Agreement, will be duly and validly issued, fully paid and non-assessable and free from all taxes and Liens with respect to the issue thereof, with the holders thereof being entitled to all rights accorded to a holder of Common Stock, and will not be issued in violation of, or subject to, any preemptive or similar rights of any Person. The Conversion Shares issuable upon conversion of the New Notes have been duly authorized and, when issued upon any such conversion, will be duly and validly issued, fully paid and non-assessable and free from all taxes and Liens with respect to the issue thereof, with the holders thereof being entitled to all rights accorded to a holder of Common Stock, and will not be issued in violation of, or subject to, any preemptive or similar rights of any Person. The Warrant Shares issuable upon exercise of, or otherwise pursuant to, the Warrants have been duly authorized and, when issued upon exercise of, or otherwise pursuant to, the Warrants, will be duly and validly issued, fully paid and non-assessable and free from all taxes and Liens with respect to the issue thereof, with the holders thereof being entitled to all rights accorded to a holder of Common Stock, and will not be issued in violation of, or subject to, any preemptive or similar rights of any Person. All of the shares of Stock of the Company that are authorized, issued and outstanding and reserved for issuance are set forth in Section 6(q) of the Disclosure Schedule (provided the outstanding shares of Common Stock are as of February 15, 2023, with any changes thereafter and prior to the date this representation is made relating solely to awards under an Approved Stock Plan). The Company has reserved from its authorized but unissued shares of Common Stock, solely for the purpose of effecting conversions of New Notes in accordance with the New Notes Indenture and exercise of any Warrants, a number of shares of Common Stock that reflects the full amount of Conversion Shares and Warrant Shares issuable upon the conversion of the New Notes or exercise of the Warrants, without regard to the NYSE Share Cap or any other limitation or restriction on the conversion or exercise thereof. Except as disclosed in Section 6(q) and 6(jj) of the Disclosure Schedule, there are no (a) Stock options or other Stock incentive plans, employee Stock purchase plans or other plans, programs or arrangements of the Company or any of its Subsidiaries under which Stock options, Stock or other Stock-based or Stock-linked awards are issued or issuable to officers, directors, employees, consultants or other Persons, (b) outstanding options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into or exchangeable or exercisable for, any Stock of the Company or any of its Subsidiaries, or contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to issue additional Stock of the Company or any of its Subsidiaries, or options, warrants or scrip for rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into or exercisable or exchangeable for, any shares of Stock of the

Company or any of its Subsidiaries, (c) agreements by which the Company or any of its Subsidiaries is obligated to register the sale of any of their Stock or other securities under the Securities Act (except the Registration Rights Agreement), (d) outstanding Stock or other securities or instruments of the Company or any of its Subsidiaries that contain any redemption (mandatory or otherwise) or similar provisions, or contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to redeem a security of the Company or any of its Subsidiaries, (e) Stock or other securities or instruments containing anti-dilution or similar provisions that may be triggered by the issuance of securities of the Company or any of its Subsidiaries or (f) stock appreciation rights or “phantom stock” plans or agreements or any similar plans or agreements to which the Company or any of its Subsidiaries is a party or by which the Company or any of its Subsidiaries is otherwise subject or bound. There are no (i) stockholders’ agreements, voting agreements or similar agreements to which the Company or any of its Subsidiaries is a party or by which the Company or any of its Subsidiaries is otherwise subject or bound, (ii) preemptive rights or any other similar rights to which any Stock of the Company or any of its Subsidiaries is subject or (iii) any material restrictions upon the voting or transfer of any Stock of the Company or any of its Subsidiaries (other than restrictions on transfer imposed by U.S. federal and state securities laws). The Company has received all required consents of its equity holders, warrant holders and other security holders to waive any applicable anti-dilution provision or other adjustment of any other class or series of Stock of the Company and of any outstanding warrants or Convertible Securities if any, that would otherwise be triggered by reason of the issuance of the New Shares, the New Notes, the Conversion Shares, the Warrants or the Warrant Shares. The issuance and delivery of the New Shares and the New Notes does not and, assuming full conversion of the New Notes and exercise of any Warrants, neither the conversion of the New Notes nor the exercise of the Warrants will: (A) require approval from any Governmental Authority; (B) obligate the Company to offer to issue, or issue, shares of Common Stock or other securities to any Person (other than the Investors); and (C) result in a right of any holder of the Company’s securities to adjust the exercise, conversion, exchange or reset price under, and will not result in any other adjustments (automatic or otherwise) under, any securities of the Company. The Company has filed with the Commission correct and complete copies of the Company’s Organizational Documents and any amendments, restatements, supplements or modifications thereto, and all other documents, agreements and instruments containing the terms of all Stock and other securities of the Company, including Stock convertible into, or exercisable or exchangeable for, Common Stock or other Stock of the Company or any of its Subsidiaries, and the material rights of the holders thereof in respect thereto.

(r) Health Care Matters.

(i) Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, neither the Company nor any of its Subsidiaries is in violation of any applicable Health Care Laws.

(ii) Neither the Company nor any of its Subsidiaries, nor any of its employees, nor any of its agents, nor any manager, director, officer, owner, member, employee or independent contractor thereof in their capacity as such or otherwise relating to the Company or any of its Subsidiaries: (i) is a party to a corporate integrity agreement, deferred prosecution agreement or other compliance agreement with the Office of Inspector General or other Governmental Authority; (ii) is excluded, debarred, terminated or suspended from participation in any Government Program; (iii) is or has been convicted of any criminal offenses relating to the delivery of an item or service under any Government Program or other payor, fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct in connection with the delivery of a healthcare item or service; and no such agreement or action is pending or threatened; or (iv) is a defendant in any unsealed qui tam, False Claims Act or similar action.

(iii) The Company and each of its Subsidiaries has the requisite provider number to bill Medicare (to the extent such Person participates in Medicare), the respective Medicaid program in the state or states in which such Person operates (to the extent such Person participates in the Medicaid program in such state or states), and all other Government Programs that the Company or any Subsidiary currently bills. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect: (1) to the Company's knowledge, neither the Company nor any of its Subsidiaries is currently subject to any audit, claim, dispute or action by or against any payor, or received any written notice that it is the subject of any inspection, investigation or audit by any Governmental Authority or payor with respect to participation in any Government Program or other payor program, and (2) there is no investigation, audit, claim review, or other action pending with respect to any the Company or any of its Subsidiaries or, to the knowledge of the Company or any of its Subsidiaries, threatened in writing, which would reasonably be expected to result in a revocation, suspension, termination, probation, restriction, limitation or non-renewal of any provider number issued to the Company or any of its Subsidiaries or result in the exclusion of the Company or any of its Subsidiaries from Medicare or Medicaid. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, to the Company's knowledge, there is not any action pending, or threatened in writing, pursuant to which any Governmental Authority seeks to impose material sanctions with respect to the Company's business or any of the Company's Subsidiaries' businesses.

(s) Material Agreements. The SEC Documents include true, correct and complete detail of all contracts, agreements, leases instruments and commitments to which the Company and each of its Subsidiaries are a party or by which they are bound, that involve any of the following (collectively, the "Material Agreements"): (a) the termination or breach of which would reasonably be expected to have a Material Adverse Effect; (b) the transfer or license of any Material IP to or from the Company or any of its Subsidiaries (other than normal non-exclusive and use customer licenses entered into with customers of the Company or any of its Subsidiaries in the ordinary course and licenses to the Company or any of its Subsidiaries for off-the-shelf software that is available on standard terms through commercial distributors); or (c) the material restriction of or otherwise materially and adversely affecting the Company's or any of its Subsidiaries' exclusive right to develop, manufacture, assemble, distribute, market, sell or otherwise

exploit its products or services (whether by territorial or other means) or of the Company or any of its Subsidiaries from freely engaging in any business or competing anywhere in the world in any material respect. Neither the Company nor any of its Subsidiaries is in breach or default under any Material Agreement, and, to the knowledge of the Company, no other party to a Material Agreement is in default or breach thereunder.

(t) Use of Proceeds; Margin Stock. The proceeds received from the sale of the Subscription Transaction New Notes to the Subscribing Investors are intended to be and shall be used for the purposes set forth in the section entitled "Use of Proceeds" in the New Notes Indenture. Neither the Company nor any of its Subsidiaries is engaged principally, or as one of its important activities, in the business of purchasing or selling Margin Stock or extending credit for the purpose of purchasing or carrying Margin Stock. As of the Closing Date, neither the Company nor any Subsidiary of the Company owns any Margin Stock. None of the issuance, sale or delivery of the Securities contemplated by the Transaction Documents, nor the acceptance of any consideration in respect thereof, including for the avoidance of doubt, the Exchange Consideration, nor the application of any of the proceeds of the Transactions as described in the section entitled "Use of Proceeds" of the New Notes Indenture, will violate Regulation T, U, or X of the Federal Reserve Board or any other regulation of the Federal Reserve Board.

(u) Environmental Matters. Except where any failures to comply would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, each of the Company and its Subsidiaries (a) is and for the past three (3) years have been in compliance with all applicable Environmental Laws, including obtaining and maintaining all Authorizations and permits required by any applicable Environmental Law, (b) is not party to, and no Real Estate currently (or to the knowledge of the Company, previously) owned, leased, subleased, operated or otherwise occupied by or for any such Person is subject to or the subject of, any contractual obligation or any pending or, to the knowledge of the Company, threatened, Proceeding, audit, Lien, demand, dispute or notice of violation or of potential liability or similar notice relating in any manner to any Environmental Law, (c) has not caused or suffered to occur a release of hazardous materials at, to or from any Real Estate, (d) does not currently (and, to the knowledge of the Company, did not at any time previously) own, lease, sublease, operate or otherwise occupy no Real Estate that is contaminated by any Hazardous Materials and (e) is not, and has not been, engaged in, and has not permitted any current or former tenant to engage in, operations in violation of any Environmental Law and knows of no facts, circumstances or conditions reasonably constituting notice of a violation of any Environmental Law, including receipt of any information request or notice of potential responsibility under the Comprehensive Environmental Response, Compensation and Liability Act or other Environmental Laws.

(v) Investment Company Act. None of the Company, any Person controlling the Company or any Subsidiary of the Company is an "investment company," or a company "controlled" by an "investment company," within the meaning of the Investment Company Act, or otherwise registered or required to be registered under, or subject to restrictions imposed, by the Investment Company Act.

(w) Labor Relations. There is no collective bargaining agreement with a union, labor organization, works council or similar representative covering any employee of the Company or any Subsidiary of the Company, (b) no petition for certification or election of any such representative is existing or pending with respect to any employee of the Company or any Subsidiary of the Company and (c) to the knowledge of the Company, no such representative has sought certification or recognition with respect to any employee of the Company or any Subsidiary of the Company. There are no strikes, picketing, work stoppages, slowdowns or lockouts existing, pending (or, to the knowledge of the Company, threatened) against or involving the Company or any Subsidiary of the Company, in each case, that would reasonably be expected to have a Material Adverse Effect.

(x) [Reserved].

(y) [Reserved].

(z) Disclosure. None of the Company's filings with the Commission nor the 2022 10-K contains any untrue statement of a material fact or omits any statement of material fact necessary in order to make the statements therein, in the light of the circumstances under which they are or were made, not misleading. None of the representations or warranties contained in any Transaction Document or any other document or information furnished by or on behalf of the Company or any of its Subsidiaries in connection with any Transaction Document and the Transactions, when taken as a whole, contains any untrue statement of a material fact or omits any material fact required to be stated therein or necessary to make the statements made therein, in light of the circumstances under which they are made, not materially misleading as of the time when made or delivered; provided that, with respect to projected financial information, the Company represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time (it being understood that such projected financial information is not to be viewed as facts, and that no assurances can be given that any particular projections will be realized and that actual results during the period or periods covered by any such projections may differ from the projected results and such differences may be material).

(aa) Certain Federal Regulations. The Company and each Subsidiary of the Company is in compliance in all material respects with all U.S. economic sanctions laws, executive orders and implementing regulations ("Sanctions") as administered by the U.S. Treasury Department's Office of Foreign Assets Control ("OFAC") and the U.S. State Department. Neither the Company nor any Subsidiary of the Company (a) is a Person on the list of the Specially Designated Nationals and Blocked Persons (the "SDN List"), (b) is a Person who is otherwise the target of U.S. economic sanctions laws such that a U.S. Person cannot deal or otherwise engage in business transactions with such Person, (c) is a Person organized or resident in a country or territory subject to comprehensive Sanctions (as of the date of this Agreement, Cuba, Iran, North Korea, Syria, the Crimea region of Ukraine, the so-called Donetsk People's Republic, and the so-called Luhansk People's Republic, each a "Sanctioned Country"), or (d) is 50% or more owned by, or acts for or on behalf of, any Person on the SDN List or a government of a Sanctioned Country such

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that, in the case of each of the foregoing clauses, the Company or any Subsidiary of the Company under, this Agreement or any other Transaction Document would be prohibited by U.S. law. The Company and each Subsidiary of the Company is in compliance with all laws related to terrorism or money laundering ("**Anti-Money Laundering Laws**") including: (i) all applicable requirements of the Currency and Foreign Transactions Reporting Act of 1970 (31 U.S.C. 5311 et. seq., (the Bank Secrecy Act)), as amended by Title III of the USA Patriot Act, and (ii) other applicable federal or state laws relating to "know your customer" or anti-money laundering rules and regulations. No Proceeding by or before any court or Governmental Authority with respect to compliance by the Company or any Subsidiary of the Company with any such Anti-Money Laundering Laws is pending or, to the knowledge of the Company and each Subsidiary of the Company, threatened. The Company and each Subsidiary of the Company is in compliance in all material respects with all applicable anti-corruption laws, including the U.S. Foreign Corrupt Practices Act of 1977 ("**FCPA**") and the U.K. Bribery Act 2010 ("**Anti-Corruption Laws**"). Neither the Company or any Subsidiary of the Company, nor to the knowledge of the Company or any Subsidiary thereof, any director, officer, agent, employee or other Person acting on behalf of the Company or any Subsidiary of the Company, has taken any action, directly or indirectly, that would result in a violation of applicable Anti-Corruption Laws. The Company maintains and implements policies and procedures designed to ensure compliance by the Company, its Subsidiaries and their respective directors, officers, employees and agents with Sanctions, Anti-Money Laundering Laws and Anti-Corruption Laws.

(bb) Securities Law and Principal Market Matters.

(i) The Company and its Subsidiaries are in all material respects in compliance with applicable provisions of the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations thereunder.

(ii) Neither the Company nor any of its Subsidiaries nor, to the Company's knowledge, any director, officer or employee, of the Company or any of its Subsidiaries, has received or otherwise obtained any material complaint, allegation, assertion or claim, whether written or oral, regarding the accounting or auditing practices, procedures, methodologies or methods of the Company or any of its Subsidiaries or its internal accounting controls, including any complaint, allegation, assertion or claim that the Company or any of its Subsidiaries has engaged in questionable accounting or auditing practices. No attorney representing the Company or any of its Subsidiaries, whether or not employed by the Company or any of its Subsidiaries, has reported evidence of a material violation of securities laws or breach of fiduciary duty or similar violation by the Company or any of its Subsidiaries or any of their respective officers, directors, employees or agents to the Company's or any of its Subsidiaries' board of directors (or equivalent governing body) or any committee thereof or to any director (or equivalent person) or officer of the Company or any of its Subsidiaries. There have been no internal or Commission investigations regarding accounting or revenue recognition discussed with, reviewed by or initiated at the direction of the chief executive officer, the principal financial officer or the principal accounting officer (in each case, or officer holding such equivalent position) of the Company or any of its Subsidiaries, the Company's or any of its Subsidiaries' board of directors (or equivalent governing body) or any committee thereof.

(iii) The Company is not, and never shall be, a "shell company" (as defined in Rule 12b-2 under the Exchange Act) and is not an issuer of a type identified in, or subject to, Rule 144(i)(1) under the Securities Act. The Company is eligible to register the New Shares, the Conversion Shares and the Warrant Shares for resale by the holders thereof on a registration statement on Form S-3 under the Securities Act. The Commission has never issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company under the Securities Act or the Exchange Act.

(iv) Assuming the accuracy of the representations and warranties of each of the Investors in this Agreement and each of the Other Investors in the Other Agreements, the offer, sale or exchange, as applicable, and issuance by the Company of the Securities is exempt from registration under the Securities Act (pursuant to Section 4(a)(2) thereof and/or Rule 506 of Regulation D thereunder), any prospectus delivery requirements under the Securities Act and applicable state securities laws.

(v) The Company acknowledges and agrees that (A) for purposes of Rule 144 under the Securities Act, each Investor's holding period for its Exchange Transaction New Securities, and any Conversion Shares issuable upon conversion thereof, shall be deemed to have commenced on the date such Investor acquired its Exchanged Old Notes, and (B) no Exchange Transaction New Securities, nor any Conversion Shares issuable upon conversion thereof, shall bear any legend, or be subject to any stop transfer or similar instructions, restricting the sale or transferability thereof or be represented by certificates assigned a restricted CUSIP number.

(vi) [Reserved.]

(vii) Neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf, has engaged or will engage in any form of general solicitation or general advertising (within the meaning of Regulation D under the Securities Act) in connection with the offer, sale or exchange, or issuance of the Securities.

(viii) Neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made, or will make, any offers or sales of any Stock or other securities, or solicited or will solicit any offers to buy any Stock or other securities, under circumstances that would require registration of any of the Securities under the Securities Act or cause this offering of the Securities to be integrated with any other offerings by the Company for purposes of any applicable stockholder approval provisions of the Principal Market or any other authority.

(ix) The Common Stock is registered under Section 12(b)(1) of the Exchange Act, and neither the Company nor any of its Subsidiaries has taken, or will take, any action designed to terminate, or that is likely to have the effect of terminating, the registration of the Common Stock under the Exchange Act; nor has the Company or any of its Subsidiaries received any notification that the Commission is contemplating terminating such registration.

(x) The Company has not, or, to the knowledge of the Company, any of its respective officers, directors or Affiliates and anyone acting on any such Person's behalf has not, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of the Common Stock of any other security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company.

(xi) Neither the Company nor any of its Subsidiaries is in violation of any of the rules, regulations or requirements of the Principal Market, and, to the knowledge of the Company and its Subsidiaries, there are no facts or circumstances that would reasonably lead to delisting or suspension or termination of trading of the Common Stock on the Principal Market. Since February 11, 2015, (i) the Common Stock has been listed or designated for quotation, as applicable, on the Principal Market, (ii) trading in the Common Stock has not been suspended by the Commission or the Principal Market, and (iii) neither the Company nor any of its Subsidiaries has received any communication, written or oral, from the Commission or the Principal Market regarding the suspension or termination of trading of the Common Stock on the Principal Market. The Transactions, and any other transactions contemplated by this Agreement and the other Transaction Documents, including the issuance of the New Shares, the Conversion Shares and the Warrant Shares hereunder and thereunder, do not contravene, or (except as expressly provided in Section 6(hh)(ii)) require stockholder approval pursuant to, the rules and regulations of the Principal Market. The New Shares, the Conversion Shares and the Warrant Shares have been approved for listing on the Principal Market, subject to official notice of issuance.

(xii) The Common Stock is, and the New Notes will be, prior to the Closing Date, eligible for clearing through the DTC, through its Deposit/Withdrawal At Custodian (DWAC) system, and the Company is eligible for and participating in the Direct Registration System (DRS) of DTC with respect to the Securities. The New Notes Trustee and the transfer agent for the Common Stock are participants in, and the Securities are eligible for transfer pursuant to, DTC's Fast Automated Securities Transfer Program. The Securities are not, and have not at any time been, subject to any DTC "chill," "freeze" or similar restriction with respect to any DTC services, including the clearing of transactions in shares of Common Stock through DTC.

(xiii) Following the filing of the 2022 10-K or any other document other than the Transactions, no event, liability, development or circumstance shall then have occurred or existed, or shall then be contemplated to occur, with respect to the Company or any of its Subsidiaries, or any of its or their business, properties, prospects, operations or financial condition, (i) that would be required to be disclosed by the Company under applicable securities laws on a registration statement on Form S-1 filed with the Commission relating to an issuance and sale by the Company of Common Stock or other securities or (ii) that, under applicable securities laws, is required to have been, or be, publicly disclosed by the Company (on Commission Form 8-K otherwise) prior to, on or within four (4) Business Days after the date this representation is made, and, in either case, that shall not have been publicly disclosed by the Company at least one (1) Business Day prior to the date this representation is made. Other than information with respect to the Transactions publicly disclosed by the Company in the Announcing Form 8-K and any information included in the 2022 10-K or earnings release for the year ended December 31, 2022 (provided that such earnings release shall be filed or furnished as an exhibit to a Form 8-K filed with the Commission at or prior to 8:30 a.m. (New York City time) on the first Business Day following the date of this Agreement), none of the Company nor any of its officers, directors (or equivalent persons), Affiliates, attorneys, agents or representatives or other Persons acting on their behalf has provided or made available to any Investor or its Affiliates, attorneys, agents or representatives with any information that constitutes or would be deemed to constitute MNPI (as defined below).

(cc) Trust Indenture Act. Assuming the accuracy of the representations and warranties of each of the Investors contained herein and of the Other Investors contained in the Other Agreements, it is not necessary to qualify the New Notes Indenture under the Trust Indenture Act of 1939, as amended, in connection with the Transactions.

(dd) Application of Takeover Provisions; Rights Agreement. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination or other similar anti-takeover provision under the Company's Organizational Documents or the laws of the State of Delaware that is or will become applicable to any of the Deerfield Holders as a result of the transactions contemplated by the Transaction Documents and the Company's fulfilling its obligations with respect thereto, including the Company's issuance of the Securities and the Deerfield Holders' ownership of the Securities. The Company has not adopted a stockholders rights plan (or "poison pill") or similar arrangement relating to accumulations of beneficial ownership of the Company's common stock or a change in control of the Company.

(ee) Brokers Fees. Other than any fees to be paid to Goldman Sachs & Co. LLC, Perella Weinberg Partners and J. Wood Capital Advisors LLC as financial advisors to the Company (the "Financial Advisors"), there are no fees, costs, expenses and commissions of any placement agent, broker or financial adviser relating to or arising out of the transactions contemplated by the Transaction Documents will be payable by the Company or any of its Affiliates with respect to the Transactions. The Company and the Guarantors will pay, and hold each of the Investors harmless against, any liability, loss or expense (including attorneys' fees, costs and expenses) arising in connection with any claim for any such payment contemplated herein that may be due in connection with the Transactions.

(ff) Status as Senior Indebtedness. The New Guarantors are secured first-priority Indebtedness of the Company and the Guarantors and are senior in right and priority of payment to all other Indebtedness (actual or contingent) of the Company and each Guarantor (except as otherwise required by Applicable Law, and except as otherwise permitted under the New Notes Indenture) no Obligations arising hereunder or under any Transaction Documents are expressly subordinated to any other Indebtedness.

(gg) Cybersecurity; Data Protection. The Company and its Subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "**IT Systems**") are adequate for, and operate and perform in all material respects as required in connection with, the operation of the business of the Company and its Subsidiaries as currently conducted, free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company and its Subsidiaries have implemented and maintained commercially reasonable controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data (including all personal, personally identifiable, sensitive, confidential or regulated data ("**Personal Data**")) used in connection with their businesses, and there have been no breaches, violations, outages or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company and its Subsidiaries are presently in material compliance with all applicable data protection laws or statutes, including the European Union General Data Protection Regulation, the California Consumer Privacy Act and any other U.S. state and federal or international laws and regulations regulating Personal Data, and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification, except where such failure would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(hh) Approvals; Voting Requirements; DGCL 203.

(i) The Board of Directors has, through a unanimous written consent, (A) declared that the Transactions are advisable and in the best interests of the Company, (B) approved resolutions authorizing the entry into, and performance under, the Transaction Documents and the consummation of the Transactions and the other transactions contemplated thereby, and (C) approved and resolved to recommend that the Company's stockholders vote in favor of the Proposal (as defined below).

(ii) The only vote of the Company required for the Transaction Documents and the Transactions, including, as applicable and for the avoidance of doubt, the issuance of the New Shares, the Conversion Shares and the Warrant Shares, under the Organizational Documents of the Company, the Delaware General Corporation Law, as amended (“**DGCL**”), and the rules and regulations of the Principal Market or otherwise, is the affirmative vote of the holders of a majority of the shares of Common Stock present in person or represented by proxy at a duly called meeting of the Company’s stockholders at which the requisite quorum is present of a proposal to approve the issuance of any Conversion Shares issuable upon conversion of the Series A New Notes and any Warrant Shares issuable upon exercise of, or otherwise pursuant to, any Warrants that may be issued in respect of the Series A New Notes (“**Series A Warrants**”), in each case, in excess of the limitations imposed by NYSE Listing Standards Rule 312.03, solely for purposes of satisfying the listing standards of the Principal Market (the “**Proposal**,” and the receipt of sufficient votes required to approve the Proposal is being referred to herein as the “**Stockholder Approval**”). No approval of the stockholders of the Company is required for (i) the issuance of the New Shares, (ii) the issuance of any Conversion Shares issuable upon conversion of the Series A New Notes not in excess of the NYSE Share Cap, (iii) the issuance of any Conversion Shares issuable upon conversion of the Series B New Notes, (iv) the issuance of any Warrant Shares issuable upon exercise of, or otherwise pursuant to, any Series A Warrants not in excess of the NYSE Share Cap, (v) the issuance of any Warrant Shares issuable upon exercise of any Warrants that may be issued in respect of the Series B New Notes or (vi) the payment of any Cash Settlement Amounts in respect of any Excess Conversion Shares.

(iii) The action taken by the Board constitutes approval of the Transactions under the provisions of Section 203 of the DGCL, such that Section 203 of the DGCL does not apply to the Transaction Documents or the Transactions, and such approval has not been amended, rescinded or modified. No other state takeover, anti-takeover, moratorium, fair price, interested stockholder, business combination or similar statute or rule is applicable to the Transactions.

(ii) Major Transactions. No Major Transaction, Organic Change or Stock Event has occurred, and the Company and the Guarantors have not taken, or otherwise agreed to take, any actions that would reasonably be executed to result in a Major Transaction, Organic Change or Stock Event.

(jj) Other Agreements. Each of the Other Agreements is listed on Disclosure Schedule 6(jj) attached hereto, and is substantially similar to this Agreement, including, but not limited to, with respect to the provisions of representations and warranties by each of the Other Investors and the undertaking of obligations by such Other Investors, except that such Other Agreements do not include certain provisions regarding MNPI (as defined below) or expenses similar to those contained herein and do not include certain other provisions contained herein. Other than the Other Agreements, the Company has not entered into any side letters or agreements with respect to any Other Investor (or affiliate thereof) with respect to their direct or indirect investment in the Company. The Other Agreements reflect the same economic and other material terms as this Agreement except as provided above and such Other Agreements are not more advantageous in any manner with respect to any Other Investor when compared to the terms of this Agreement and the terms agreed to and received by each of the Investors hereunder.]

7. Representations and Warranties of the Investor. Investor, jointly, hereby represents and warrants:

- (a) Organization and Authority. Such Investor is duly formed, validly existing and in good standing under the laws of the jurisdiction of its formation, and has all requisite corporate (or other applicable entity) power and authority to execute and deliver this Agreement and to carry out and perform its obligations under the terms hereof.
- (b) Ownership of Exchanged Old Notes. Such Investor is the beneficial owner of (or otherwise has sole discretionary management authority with respect to) its Exchanged Old Notes. Upon delivery to the Company by such Investor of its Exchanged Old Notes, and upon such Investor's receipt of its Exchange Transaction New Securities, as consideration in respect thereof as set forth herein, pursuant to this Agreement, good and valid title to the Exchanged Old Notes delivered by such Investor will pass to the Company, free and clear of any Liens imposed upon such Investor or its assets or as a result of any action taken thereby.
- (c) Non-Contravention. The execution and delivery of this Agreement by such Investor and the performance by such Investor of its obligations hereunder will not violate (1) any law, rule or regulation to which such Investor is subject or (2) the charter or bylaws (or equivalent organizational documents) of such Investor, except, in the case of clause (1), violations as would not reasonably be expected to materially and adversely affect such Investor's ability to perform its obligations under the Transaction Documents or consummate the Transactions on a timely basis.
- (d) Acquisition for Own Account. Such Investor is acquiring the Securities for its own account, as principal, and not with a view towards, or for resale in connection with, the public sale or distribution thereof, except pursuant to sales registered under, or exempted from, the registration requirements of the Securities Act; *provided, however*, that by making the representations herein, such Investor does not agree to hold any of the Securities for any minimum or other specific term and reserves the right to assign, transfer or otherwise dispose of any of the Securities at any time pursuant to an effective registration statement under, or an exemption from the registration requirements of, the Securities Act.
- (e) Investor Status. Such Investor is (i) an "accredited investor" as that term is defined in Rule 501(a) of Regulation D under the Securities Act, (ii) a "qualified institutional buyer" (as that term is defined in Rule 144A of the Securities Act) and (iii) an "Institutional Account" as defined in FINRA Rule 4512(c), and has such knowledge and experience in business and financial matters so as to be capable of evaluating the merits and risks of its investment in the Securities. Such Investor understands and accepts that acquiring the New Notes in the Transactions involves risks, including those described in the SEC Documents. Such Investor is a sophisticated participant in the transactions

contemplated hereby and has such knowledge and experience in financial matters as to be capable of evaluating the merits and risks of an investment in the New Notes, is experienced in investing in capital markets and is able to bear the economic risk associated with an investment in the Securities. [Each Investor agrees to furnish any additional information reasonably requested by the Company or any of its affiliates to assure compliance with applicable U.S. federal and state securities laws in connection with the Transactions.]

(f) Exemptions. Such Investor understands that the Securities are being offered and sold, or delivered in exchange for Old Notes, as applicable, to it in reliance on specific exemptions from the registration requirements of the United States federal and state securities laws and that the Company is relying in part upon the truth and accuracy of, and such Investor's compliance with, the representations, warranties, agreements, acknowledgments and understandings of such Investor set forth herein in order to determine the availability of such exemptions.

(g) Diligence. Such Investor and its advisors, if any, have been furnished with [and carefully reviewed] all materials relating to the business, finances and operations of the Company and its Subsidiaries and materials relating to the offer and sale of the Securities that have been requested by such Investor. Such Investor and its advisors, if any, have been afforded the opportunity to ask questions of and receive answers from the Company concerning the terms and conditions of an investment in the Securities. [No statement or printed material which is contrary to the disclosure documents has been made or given to such Investor by or on behalf of the Company.] None of any such inquiries, any other due diligence investigations conducted by any such Investor or its advisors or its representatives, if any, and the making by such Investor or representations and warranties pursuant to this Section 7 shall modify, amend or otherwise affect such Investor's right to rely on the representations, warranties, covenants and agreements of the Company and its Subsidiaries contained in Section 6 and elsewhere in this Agreement and the other Transaction Documents.

(h) No Recommendation or Endorsement. Such Investor understands that no United States federal or state agency or any other government or Governmental Authority has passed on or made any recommendation or endorsement of the Securities or the fairness or suitability of the investment in the Securities nor have such authorities passed upon or endorsed the merits of the offering of the Securities.

(i) Accounts. If such Investor is exchanging any Old Notes or acquiring any of the New Notes or New Shares as a fiduciary or agent for one or more accounts, it represents that it has (A) the requisite investment discretion with respect to each such account necessary to effect the Transactions, (B) full power to make the foregoing representations, warranties and covenants on behalf of such account; and (C) contractual authority with respect to each such account.

(j) Jurisdiction. Such Investor is a resident of the state set forth on Exhibit A-5 hereto.

(k) Without limiting the right of such Investor to rely on or enforce the representations, warranties, covenants and agreements of the Company and/or each Guarantor in any Transaction Document, such Investor confirms that it is not relying on any communication (i) (written or oral) of the Company, the Financial Advisors or any of their respective agents or affiliates as investment advice or as a recommendation to participate in the Transactions and receive the New Securities pursuant to the terms hereof. It is understood that none of the Company, the Financial Advisors or any of their respective agents or affiliates is acting or has acted as an advisor to such Investor in deciding whether to participate in the Transactions.

(l) Without limiting the right of such Investor to rely on or enforce the representations, warranties, covenants and agreements of the Company and/or each Guarantor in any Transaction Document, such Investor confirms that none of the Financial Advisors has given any guarantee or representation as to the potential success, return, effect or benefit (either legal, regulatory, tax, financial, accounting or otherwise) of the Transactions. Without limiting the right of such Investor to rely on or enforce the representations, warranties, covenants and agreements of the Company and/or each Guarantor in any Transaction Document, in deciding to participate in the Transactions, such Investor has made its own independent decision that participation in the Transactions (as applicable) is suitable and appropriate for such Investor.

(m) Such Investor is not, and has not been for the immediately preceding three months, an "affiliate" (within the meaning of Rule 144 under the Securities Act) of the Company.

(n) Such Investor hereby confirms that its Exchanged Old Notes were either (i) acquired more than one year prior to the Closing Date or (ii) acquired from a noteholder who such Investor reasonably believed was not at the time of such sale or the immediately preceding three months, an "affiliate" (within the meaning of Rule 144 under the Securities Act) of the Company.

(o) Such Investor hereby acknowledges that the Financial Advisors do not take any responsibility for, [and] can provide no assurance as to the reliability of, the information set forth in the Transaction Documents [and such Purchaser is not relying upon, and has not relied upon, any statement, representation or warranty made by the Financial Advisors, any of their affiliates or any of their control persons, officers, directors or employees, in making its investment or decision to invest in the Company. Such Investor agrees that the none of the Financial Advisors or any of their respective agents, affiliates, control persons, officers, directors or employees shall be liable to any Investor in connection with its purchase of the Securities].

(p) Such Investor acknowledges that the terms of the Transactions have been mutually negotiated between such Investor and the Company. Such Investor was given a meaningful opportunity to negotiate the terms of the Transactions.

(q) Such Investor acknowledges the Company intends to pay an advisory fee to the Financial Advisors in respect of the Transactions. Such Investor further acknowledges that it has been advised that J. Wood Capital Advisors LLC intends to participate in the Additional Subscription Transaction and purchase \$ aggregate principal amount of Series B New Notes.

(r) Such Investor will, upon request, execute any agreements, provide information or certifications reasonably requested by the Company, the Old Notes Trustee, the New Notes Trustee or the Transfer Agent to complete the Transactions.

(s) Such Investor's participation in the Transactions was not conditioned by the Company on such Investors' exchange of a minimum principal amount of Old Notes.

(t) Such Investor acknowledges that it had a sufficient amount of time to consider whether to participate in the Transactions and that neither the Company nor the Financial Advisors has placed any pressure on such Investor to respond to the opportunity to participate in the Transactions. Such Investor acknowledges that it did not become aware of any aspect of the Transactions through any form of general solicitation or advertising within the meaning of Rule 502 under the Securities Act.

(u) Such Investor understands that the Financial Advisors will rely upon the truth and accuracy of the foregoing representations and warranties and agrees that if any of the representations and warranties deemed to have been made by it are no longer accurate, such Investor shall promptly notify the Financial Advisors prior to the Closing Date.

8. Agreements of the Company. The Company agrees with the Investors that:

(a) Reservation of Shares. From and after the date hereof, the Company shall at all times reserve and keep available (free of preemptive or similar rights) from its authorized but unissued shares of Common Stock, solely for the purpose of effecting conversions of the New Notes in accordance with the New Notes Indenture and exercise of any Warrants, such number of shares of Common Stock as shall from time to time be sufficient to effect the conversion of the entire amount of the New Notes convertible under the New Notes Indenture, together with accrued and unpaid interest thereon, and the exercise in full of any Warrants issued or issuable pursuant to the New Notes Indenture (without giving effect to the Beneficial Ownership Cap, the NYSE Share Cap, the Beneficial Ownership Limitation (as defined in the Warrants), the Remaining NYSE Share Cap Amount, or any other restriction or limitation on conversion or exercise contained in the New Notes Indenture or the Warrants); and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of the entire amount of the New Notes convertible under the New Notes Indenture or the exercise in full of any Warrants issued or issuable pursuant to the New Notes Indenture (without giving effect to the Beneficial Ownership Cap, the NYSE Share Cap, the Beneficial Ownership Limitation, the Remaining NYSE Share Cap Amount, or any other restriction or limitation on conversion or exercise contained in the New Notes Indenture or the Warrants), the Company will use reasonable best efforts to take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to at least such number of shares as shall be sufficient for such purpose.

(b) Certain Stockholders' Rights Plans. At any time after the Closing, the Company shall not adopt any stockholder rights agreement, "poison pill" or similar anti-takeover agreement or plan that is applicable to Securities held by any of the Investors unless the Company has excluded such Investors from the definition of "acquiring person" (or such similar term) as such term is defined in such anti-takeover agreement to the extent of such Investor's beneficial ownership of the Securities owned as of the date any such agreement or plan is adopted by the Company.

(c) Securities Law Filings. If the Company concludes it is required, the Company, with the prior written consent of the Financial Advisors, shall timely file a Form D with respect to the offering of the Securities as required by Rule 503 under the Securities Act. The Company shall make all filings, if any, under applicable securities or "Blue Sky" laws of the states of the United States as the Company concludes are necessary in connection with the issuance of the Securities.

(d) Listing. The Company will have submitted on prior to the Closing Date a supplemental listing application to the NYSE for the listing of the New Shares, Conversion Shares and Warrant Shares on the Principal Market and will use commercially reasonable best efforts to maintain the listing of, the New Shares, the Conversion Shares and the Warrant Shares on the Principal Market.

(e) Disclosure; No MNPI.

(i) At or prior to 8:30 a.m. (New York City time) on the first Business Day following the date of this Agreement, the Company shall file with the Commission a Form 8-K describing the material terms of the Transaction Documents and the Transactions and including as exhibits to such Form 8-K this Agreement, the New Notes Indenture, the form of Warrant [and the Registration Rights Agreement] (such Form 8-K, the "**Announcing Form 8-K**"), and the 2022 10-K. Notwithstanding the foregoing, the Company shall not (and the Company shall not permit any of its Affiliates to) issue any press releases or any other public statements with respect to the transactions contemplated by any Transaction Document disclosing the name of any Investor or any of its Affiliates without such Investors' prior consent; *provided, however*, that the Company shall be entitled, without the prior approval of any Investor, to make any press release or other public disclosure with respect to such transactions (i) in substantial conformity with the Announcing Form 8-K and contemporaneously therewith (which, for the avoidance of doubt, shall include filing signature pages and any other portions of the Transaction Documents filed as exhibits to the Announcing Form 8-K) and (ii) as is required by Applicable Law and regulations (provided that each Investor shall be consulted by the Company in connection with any such press release or other public disclosure prior to its release and shall be provided with a copy thereof).

(ii) [No later than 8:30 a.m. on the (i) the first Business Day following the Closing Date and (ii) the date of any termination of this Agreement pursuant to Section 14, the Company shall file with the Commission a Form 8-K disclosing the occurrence of the Closing Date and the consummation of the Transactions or, if applicable, disclosing such termination of this Agreement.

(iii) Upon the filing of the Announcing Form 8-K and the filing of this Document, the Company and its Subsidiaries shall have disclosed all material, non-public information (if any) regarding the Company and its Subsidiaries, their securities, any of their Affiliates or any other Person (“**MNPI**”) provided or made available to any Investor or any of their Affiliates, attorneys, agents or representatives by the Company or any of its Subsidiaries or any of its employees, officers, directors (or equivalent persons), attorneys, agents or representatives on or prior to the Closing Date. The Company and its Subsidiaries shall not, and shall cause each of their employees, officers, directors (or equivalent persons), Affiliates, attorneys, agents and representatives to not, provide any Investor or any of its Affiliates, attorneys, agents or representatives with any MNPI from and after the filing of the Announcing Form 8-K with the Commission without the express prior written consent of such Investor.

(iv) Notwithstanding anything to the contrary herein, in the event that the Company believes that a notice or communication to any Investor or any of their Affiliates, attorneys, agents or representatives contains MNPI, the Company shall, prior to the delivery of such notice or communication, (i) so indicate to such Investor, and such indication shall provide such Investor the means to refuse to receive such notice or communication, and in the absence of any such indication, such Investors, any other holders of the Securities and their respective Affiliates, agents and representatives shall be allowed to presume that all matters relating to such notice or communication do not constitute MNPI, and (ii) provide such notice or communication to such Investor’s Outside Counsel. Upon receipt or delivery by the Company or any Guarantor of any notice in accordance with the terms of the Transaction Documents, unless the Company or such Guarantor has in good faith determined that the matters relating to such notice do not constitute MNPI, the Company or such Guarantor shall contemporaneously (or, in the case of the Company or Guarantor’s receipt of such a notice, within one Business Day after such receipt) publicly disclose such MNPI. In the event of a breach of any of the foregoing covenants by the Company or any Guarantor or any of its Subsidiaries, any of their Affiliates, or any of their respective officers, directors (or equivalent persons), employees, attorneys, agents or representatives, in addition to any other remedies provided in the Transaction Documents or otherwise available at law or in equity, each Investor shall have the right to make a public disclosure in the form of a press release or otherwise, of the applicable MNPI without the prior approval by the Company, any Guarantor, or any of their Subsidiaries, or any of their Affiliates, officers, directors (or equivalent persons), employees, stockholders, attorneys, agents or representatives, and no Investor (nor any of their Affiliates, agents or representatives) shall have any liability to the Company, any Guarantor, or any of their Subsidiaries, any of their Affiliates or any of their respective officers, directors (or equivalent persons), employees, stockholders, attorneys, agents or representatives for any such disclosure.

(v) Notwithstanding the foregoing, ~~Document Page 830 of 970~~ the Company in good faith determines that it is necessary to disclose material non-public information to an Investor for purposes relating to any of the Transaction Documents (a "**Necessary Disclosure**"), the Company shall inform such Investor's Outside Counsel of such determination without disclosing the applicable material non-public information, and the Company and such Outside Counsel on behalf of the applicable Investor shall endeavor to agree upon a process for making such Necessary Disclosure to the applicable Investor or its representatives that is mutually acceptable to such Investor and the Company (an "**Agreed Disclosure Process**"). Thereafter, the Company shall be permitted to make such Necessary Disclosure (only) in accordance with the Agreed Disclosure Process.

(vi) The Company hereby acknowledges and agrees that no Investor (nor any of such Investor's Affiliates, attorneys, agents or representatives) shall have any duty of trust or confidence (including any obligation under any confidentiality or non-disclosure agreement entered into by such Investor) with respect to, or any obligation not to trade in any securities while aware of, any MNPI (X) provided by, or on behalf of, the Company or any of its Subsidiaries, any of their Affiliates or any of their officers, directors (or equivalent persons), employees, attorneys, agents, advisors or representatives in violation of any of the representations, warranties, covenants, provisions or agreements set forth in this Section 8(e) or in Section 6(bb)(xiii) hereof or (Y) otherwise possessed (or continued to be possessed) by any Investor (or any Affiliate, agent or representative thereof) as a result of any breach or violation by the Company or any of its Subsidiaries, any of their Affiliates or any of their officers, directors (or equivalent persons), employees, attorneys, agents or representatives of any representation, warranty, covenant, provision or agreement set forth in this Section 8(e) or in Section 6(bb)(xiii) hereof. The Company understands and acknowledges that the Investors, their Affiliates and Persons acting on their behalf will rely on such representations, warranties, covenants, provisions and agreements in effecting transactions in the Securities and other securities of the Company and of other Persons.

(vii) Notwithstanding anything to the contrary contained herein or in any Transaction Document, with respect to each Investor, the provisions of this Section 8(e) shall survive the settlement and consummation of the Transactions, the repayment or other satisfaction of the Obligations, including as a result of a conversion of any New Notes, the termination of the Indenture and thereafter for so long as such Investor holds any Securities.]

(f) Issuances of Securities. From the Closing Date until [the latest of (i)] the consummation of the Stockholder Approval, [(ii) the effective date of the first Registration Statement filed pursuant to the Registration Rights Agreement and (iii) March 7, 2025,] except as otherwise provided in the Transaction Documents, the Company shall not (a) in any manner issue or sell any Options or Convertible Securities that are convertible into or exchangeable or exercisable for shares of Common Stock at a price that varies or may vary with the market price of the Common Stock, including by way of one or more resets to a

fixed price or increases in the number of shares of Common Stock issued is reduced or a price that upon the passage of time or the occurrence of certain events automatically is reduced or is adjusted or at the option of any Person may be reduced or adjusted, whether or not based on a formulation of the then current market price of the Common Stock (other than proportional adjustments as a result of subdivisions or combinations of the Common Stock in the form of stock splits, stock dividends, reverse stock splits, combinations or recapitalizations) or (b) enter into any agreement (including any equity line of credit) whereby the Company may sell securities at a future determined price (other than pursuant to an at-the-market offering program registered under the Securities Act) [(any issuance, entry into an agreement or transaction referred to in clause (a) or (b), a "**Variable Price Transaction**"); *provided, however*, that, without limiting the rights of the Investors under Section 14.02(n) of the Indenture and Section 4(g) of any Warrants, following the later of the consummation of the Stockholder Approval and the effective date of the first Registration Statement filed pursuant to the Registration Rights Agreement, the foregoing shall not prevent (x) the Company from effecting any Variable Price Transaction so long as no Options or Convertible Securities directly or indirectly issued or issuable thereunder have a conversion, exchange or exercise price per share of Common Stock that could at any time be less than the Conversion Price or (y) the Company from including any customary full ratchet or weighted average anti-dilution provisions based upon the issuance or deemed issuance price of other securities of the Company.]

(g) Disclosure. The Company shall, and shall cause each of its Subsidiaries to, ensure that all written information, exhibits and reports furnished to any Investor, when taken as a whole in conjunction with the SEC Documents, do not and will not (or does not, as applicable) contain any untrue statement of a material fact and do not and will not omit to state any material fact or any fact necessary to make the statements contained therein not materially misleading in light of the circumstances in which made, and will promptly disclose to the Trustee, with a copy to each of the Investors, and correct any defect or error that may be discovered therein or in any Transaction Document or in the execution, acknowledgement or recordation thereof.

(h) Stockholders Meeting.

(i) The Company shall take all action necessary to duly call, give notice of, convene and hold a meeting of stockholders (such meeting, the "**Stockholders Meeting**") for the purpose of, among other matters, obtaining the Stockholder Approval (the date such approval is obtained, the "**Stockholder Approval Date**") as promptly as reasonably practicable after the Commission confirms that it has no further comments on the Proxy Statement (as defined below) or the Company otherwise determines in good faith that such Proxy Statement will not be reviewed by the Commission (subject to compliance with the 10-day waiting period set forth in Rule 14a-6 under the Exchange Act). In the event that the Company does not obtain the Stockholder Approval at the Stockholders Meeting, the Company agrees that it will seek to obtain the Stockholder Approval at any subsequent meeting of stockholders of the Company until the Stockholder Approval is obtained. Without limiting the generality of the foregoing, the Company will comply with the terms of Section 8(i) hereof with respect to each such meeting of stockholders as if it were the Stockholders Meeting.

(ii) Promptly after the Stockholder Approval is obtained, and no later than one (1) Business Day thereafter, the Company shall promptly deliver notice of the Stockholder Approval to the Trustee and each of the Investors and file with the Commission a Form 8-K disclosing the same.

(i) Proxy Material.

(i) In connection with the Stockholders Meeting, the Company will (A) as promptly following the date of this Agreement as the Company shall reasonably determine is necessary to hold the Stockholders Meeting on or prior to June 30, 2023, prepare and file with the Commission a proxy statement (any such proxy statement, as it may be amended or supplemented from time to time, the "**Proxy Statement**") related to the consideration of the Proposal at the Stockholders Meeting, (B) respond as promptly as reasonably practicable to any comments received from the Commission with respect to such filings and provide copies of such comments to each Investors that has so requested in a written request delivered to the Company (each such Investor delivering such request is referred to herein as a "**Requesting Investor**") and promptly upon receipt of such request provide copies of proposed responses to each Requesting Investor allowing for reasonable time prior to filing to allow for meaningful comment, (C) as promptly as reasonably practicable prepare and file any amendments or supplements necessary to be filed in response to any Commission comments or as otherwise required by law, (D) mail to its stockholders as promptly as reasonably practicable the Proxy Statement and all other customary proxy or other materials for meetings such as the Stockholders Meeting, (E) to the extent required by applicable law, as promptly as reasonably practicable prepare, file and distribute to the Company stockholders any supplement or amendment to the Proxy Statement if any event shall occur which requires such action at any time prior to the Stockholders Meeting, and (F) otherwise use reasonable best efforts to comply with all requirements of law applicable to any Stockholders Meeting. Each of the Investors shall cooperate with the Company in connection with the preparation of the Proxy Statement and any amendments or supplements thereto, including promptly furnishing the Company upon request with any and all information in respect of such Investor as may be required to be set forth in the Proxy Statement or any amendments or supplements thereto under applicable law. The Company will provide each Requesting Investor a reasonable opportunity to review and comment upon the Proxy Statement, or any amendments or supplements thereto, and shall give reasonable consideration to any such comments proposed, prior to mailing the Proxy Statement to the Company's stockholders. The Proxy Statement shall include the recommendation of the Board of Directors that stockholders vote in favor of the adoption of the Proposal at the Stockholders Meeting, and the Company shall use its reasonable best efforts to obtain the Stockholder Approval at the Stockholders Meeting, including by retaining and utilizing the efforts of a nationally recognized proxy solicitation firm.

(ii) If, at any time prior to the Stockholders Meeting, any information that should be included or incorporated by reference in the Proxy Statement or any of the Investors or any of their respective Affiliates should be discovered by the Company or the Investors which should be set forth in an amendment or supplement to the Proxy Statement so that the Proxy Statement shall not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they are made, not misleading, the party that discovers such information shall promptly notify the other parties and, to the extent required by applicable law, the Company shall disseminate an appropriate amendment thereof or supplement thereto describing such information to the Company's stockholders.

(iii) The Company agrees that (A) none of the information to be included or incorporated by reference in the Proxy Statement or any amendment or supplement thereto, or any other document filed with the Commission in connection with the solicitation of the Stockholder Approval at the Stockholders Meeting (all such other documents, the "**Other Filings**") shall, in the case of the Proxy Statement, at the date it is first mailed to the Company's stockholders or at the time of the Stockholders Meeting or at the time of any amendment or supplement thereof, or, in the case of any Other Filing, at the date it is first mailed to the Company's stockholders or at the date it is first filed with the Commission, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they are made, not misleading, except that no covenant is made by the Company with respect to statements made or incorporated by reference therein based on information supplied by any of the Investors or any of their Affiliates or representatives in connection with the preparation of the Proxy Statement or the Other Filings for inclusion or incorporation by reference therein, and (B) the Proxy Statement and the Other Filings that are filed by the Company shall comply as to form in all material respects with the requirements of the Exchange Act.

(iv) Each of the Investors covenants that none of the information supplied in writing by or on behalf of such Investor expressly for inclusion in the Proxy Statement or the Other Filings will, in the case of the Proxy Statement, at the date it is first mailed to the Company's stockholders or at the time of the Stockholders Meeting or at the time of any amendment or supplement thereof, or, in the case of any Other Filing, at the date it is first mailed to the Company's stockholders or at the date it is first filed with the Commission, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they are made, not misleading.

9. Conditions.

(a) The obligations of the Investors described herein shall be subject to the satisfaction or waiver of the following conditions on or prior to the Closing Date:

(i) *Representations and Warranties.* The representations and warranties of the Company contained herein shall be true and correct in all material respects on the date hereof and on and as of the Closing Date, and the Company shall have performed all applicable covenants and agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date.

(ii) *No Legal Impediment to Issuance.* No action shall have been taken and no statute, rule, regulation or order shall have been enacted, adopted or issued by any federal, state or foreign governmental or regulatory authority that would, as of the Closing Date, prevent the consummation of the Transactions; and no injunction or order of any federal, state or foreign court shall have been issued that would, as of the Closing Date, prevent the consummation of the Transactions, including, but not limited to, the issuance of the New Securities pursuant thereto.

(iii) *Discharge of Perceptive Facility.* Prior to or substantially concurrently with the issuance of the New Notes, the Perceptive Facility shall have been fully repaid and discharged and no obligations with respect thereto shall remain outstanding, and any Liens securing such obligations shall have been released.

(iv) *Legal Opinions.* Each of the Investors shall have received customary legal opinions from Latham & Watkins LLP, as counsel to the Company, Pillsbury Winthrop Shaw Pittman LLP, as counsel to the Company, Cooley LLP, as Colorado counsel to the Company and Morgan, Lewis & Bockius LLP, as Pennsylvania counsel to the Company, in form reasonably satisfactory to the Investors (or their counsel).

(v) *Officer's Certificate.* Each of the Investors shall have received on and as of the Closing Date a certificate of an executive officer of the Company and of each Guarantor who has specific knowledge of the Company's or such Guarantor's financial matters and is satisfactory to the Investors (or their counsel) (i) confirming that such officer has carefully reviewed the Transaction Documents and, to the knowledge of such officer, all representations made by the Company and the Guarantors and set forth in this Agreement are true and correct as of the Closing Date and (ii) that the Company and the Guarantors have complied with all agreements and satisfied all conditions on their part to be performed or satisfied hereunder at or prior to the Closing Date.

(vi) *Secretary's Certificate.* With respect to the New Notes Indenture, each of the Investors shall have received:

1) a certified copy of (i) the certificate of incorporation of the Company, certified as of a recent date by the Secretary of State of Delaware and (ii) the formation document of each Guarantor, certified as of a recent date by the applicable jurisdiction of formation of each Guarantor;

2) a certificate of the Secretary of the Company, as to the Closing Date and certifying:

a) that attached thereto are true and complete copies of (i) the by-laws of the Company and (ii) the governing document of each Guarantor, as in effect on the Closing Date and at all times since a date prior to the date of the resolutions described in clause b) below;

b) that attached thereto is a true and complete copy of resolutions duly adopted by the board of directors of the Company and of each Guarantor authorizing the execution, delivery and performance, as applicable, of the Transaction Documents, the Transactions and the issuance of the Securities, and any other transactions related thereto, and that such resolutions have not been modified, rescinded or amended and are in full force and effect on the Closing Date;

c) that each of the certificate of incorporation of the Company and the formation document of each Guarantor has not been amended since the date of the last amendment thereto disclosed pursuant to clause a) above; and

d) as to the incumbency and specimen signature of each officer executing the New Notes Indenture on behalf of the Company and the Guarantors; and

3) a certificate of a director or an executive officer as to the incumbency and specimen signature of the Secretary or Assistant Secretary or similar officer executing the certificate pursuant to clause 2) above.

(vii) *Solvency Certificate*. Each of the Investors (shall have received a Solvency Certificate from the Company and the Guarantors substantially in the form attached hereto as Exhibit E.

(viii) *Good Standing*. Each of the Investors shall have received on the date hereof and as of the Closing Date satisfactory evidence of the good standing of the Company and the Guarantors in their respective jurisdictions of organization and their good standing in such other jurisdictions as the Investors may reasonably request, in each case in writing or any standard form of telecommunication from the appropriate governmental authorities of such jurisdictions.

(ix) *Listing*. The Principal Market shall have completed its review of all listing applications regarding listing of the New Shares, the Conversion Shares and the Warrant Shares on the Principal Market.

(x) *Transaction Documents*. The New Note Indenture, [Security Agreement] and each of the other Transaction Documents shall have been validly entered into by, and be binding upon, all parties thereto (including, but not limited to, the Company, the Guarantors, the Trustee, the Collateral Agent and the Other Investors, as applicable) and shall be in full force and effect, and each of the Investors shall have received evidence reasonably satisfactory to such Investor to such effect.

(xi) *DTC*. The Securities shall be eligible for clearance and settlement through DTC.

(xii) *Lien Searches*. Each of the Investors shall have received the results of a recent Lien search in each of the jurisdictions where assets of the Company and the Guarantors are located, the jurisdictions of the chief executive office of each of the Company and each Guarantor, and such search shall reveal no Liens on any of the assets of the Company and the Guarantors or their respective subsidiaries except for Permitted Liens.

(xiii) *Perfection of Security Interests*. The Company and each Guarantor shall have completed, on or prior to the Closing Date, all UCC filings and other actions required in connection with the perfection of security interests in the Collateral as and to the extent contemplated by the New Notes Indenture and the Collateral Documents and to the extent contemplated by the New Notes Indenture and the Collateral Documents; provided that the Company and the Guarantors may deliver, furnish and/or cause to be furnished all of the obligations set forth on Schedule 6 to the Security Agreement within the time periods set forth therein.

(xiv) *Other Agreements*. [There shall have been no amendment, modification or waiver of any Other Agreement that materially benefits any Other Investor unless each of the Investors has been offered the same benefit, and the Company shall not have entered into any side letter or other agreements (other than the Other Agreements) that materially benefits any Other Investor or other party thereto, unless each of the Investors have been offered the same benefits.]

(b) The obligation of the Company to deliver the New Securities to be issued by it on the Closing Date to any of the of the Investors shall be subject to the satisfaction or waiver of the following conditions on or prior to the Closing Date:

(i) The representations and warranties of such Investor contained herein shall be true and correct in all material respects on the date hereof and on and as of the Closing Date, and such Investor shall have performed all applicable covenants and agreements and satisfied all conditions to be performed or satisfied hereunder at or prior to the Closing Date.

(ii) No action shall have been taken and no statute, rule, regulation or order shall have been enacted, adopted or issued by any federal, state or foreign governmental or regulatory authority that would, as of the Closing Date, prevent the consummation of the Transactions; and no injunction or order of any federal, state or foreign court shall have been issued that would, as of the Closing Date, prevent the consummation of the Transactions, including the issuance of the New Securities pursuant thereto.

10. Taxation.

(a) Each Investor acknowledges that, if such Investor is a United States person for U.S. federal income tax purposes, the Company must be provided with a correct taxpayer identification number (generally a person's social security or federal employer identification number) and certain other information on a properly completed and executed United States Internal Revenue Service ("**IRS**") Form W-9 stating that such Investor is not subject to backup withholding and that such Investor is a United States person. Each Investor further acknowledges that, if such Investor is not a United States person for U.S. federal income tax purposes, the Company must be provided with a properly completed and executed IRS Form W-8BEN, IRS Form W-8BEN-E, IRS Form W-8IMY (and all required attachments) or other applicable IRS Form W-8, attesting to that non-U.S. Investor's foreign status and certain other information, including information establishing an exemption from withholding under Sections 1471 through 1474 of the Internal Revenue Code. Each Investor further acknowledges that it may be subject to 30% U.S. federal withholding or 24% U.S. federal backup withholding on certain payments or deliveries made to such Investor unless such Investor properly establishes an exemption from, or a reduced rate of, such withholding or backup withholding. The Company and its agents shall be entitled to deduct and withhold from any consideration payable pursuant to this Agreement such amounts as are required to be deducted or withheld under Applicable Law. To the extent any such amounts are withheld and remitted to the appropriate taxing authority, such amounts shall be treated for all purposes as having been paid to such Investor to whom such amounts otherwise would have been paid.

(b) [In connection with the Transactions, each Investor shall provide the Company with a properly completed and executed IRS Form W-9.] [Unless an Investor gives a written notice to the Company otherwise, each Investor hereby represents that it is not subject to any U.S. withholding tax with respect to Old Notes Interest and is entitled to provide U.S. tax forms and required attachments indicating the same.]

(c) The Company intends this Agreement to be and hereby adopts this Agreement as a plan of reorganization for purposes of Section 368 of the Code and the income tax regulations thereunder. The parties hereto intend and agree that the Exchange Transaction and the related issuance of Series A New Notes (other than any Exchange Transaction New Securities treated as issued with respect to the accrued and unpaid interest on the Old Notes) (including the corresponding Guarantees and other related Collateral Documents) and the New Shares are part of, and pursuant to, a Plan of Recapitalization and Reorganization of the Company described in Section 368(a)(1)(E) of the Code (and any similar provision of state or local law) ("**Intended Tax Treatment**"). The parties agree to (and agree to cause their Affiliates to) file their income tax returns consistent with the Intended Tax Treatment (including by making any filings under Treasury Regulations Section 1.368-3 that are required to support such treatment), except as otherwise required by a determination within the meaning of Section 1313 of the Code.

(d) Each Investor that claims an exemption from the threshold for unpaid interest under the so-called “portfolio interest exemption” hereby represents to the Company that:

- (i) It is the sole record owner of the Exchanged Old Notes in respect of which it is providing this representation, and it (or its partners, members or beneficial owners) is the beneficial owner of such Exchanged Old Notes;
- (ii) Neither it nor any of its partners, members or beneficial owners that is claiming portfolio interest exemption is a “bank” within the meaning of Section 881(c)(3)(A) of the Code;
- (iii) Neither it nor any of its partners, members or beneficial owners that is claiming portfolio interest exemption is a “10-percent shareholder” of the Company within the meaning of Section 881(c)(3)(B) or Section 871(h)(3)(B) of the Code; and
- (iv) Neither it nor any of its partners, members or beneficial owners that is claiming portfolio interest exemption is a “controlled foreign corporation” (within the meaning of Section 881(c)(3)(C) of the Code) related to the Company (within the meaning of Section 864(d)(4) of the Code).

11. Expenses. [The Company agrees to pay or reimburse the Deerfield Holders for all reasonable costs and expenses incurred in connection with the preparation, negotiation and execution of this Agreement and the other Transaction Documents and any amendment, waiver, consent or other modification of the provisions hereof and thereof (whether or not the transactions contemplated thereby are consummated), and the consummation and administration of the transactions contemplated hereby and thereby, including the reasonable and documented fees, disbursements and other charges of legal counsel to the Deerfield Holders. The foregoing costs and expenses shall include all search, filing, recording, title insurance and appraisal charges and fees related thereto, and other out-of-pocket expenses incurred by the Deerfield Holders. All amounts due under this Section 11 shall be paid within five (5) Business Days after invoiced or demand therefor; *provided* that any amounts invoiced at least two (2) Business Days prior to the Closing Date shall be paid on the Closing Date. The agreements in this Section 11 shall survive the termination of this Agreement.]

12. Indemnification. In consideration of each Investor’s execution and delivery of this Agreement and acquiring New Securities thereunder and in addition to all of the Company’s and the Guarantors’ other obligations under the Transaction Documents, the Company and the Guarantors, jointly and severally, shall defend, protect, indemnify and hold harmless each Investor and all of their stockholders, partners, members, officers, directors, employees and direct or indirect investors and any of the foregoing persons’ agents or other representatives (including, without limitation, those retained in connection with the transactions contemplated by this Agreement) (collectively, the “**Indemnitees**”) from and against any and all actions, causes of action, suits, claims, losses, costs, penalties, fees, liabilities and damages of any kind or nature, and expenses in connection therewith (irrespective of whether any such Indemnitee is a party to the action for which indemnification hereunder is sought), and including reasonable attorneys’ fees

and disbursements (the "**Indemnified Liabilities**"), in Document Page 639 of 970 incurred by or asserted against any Indemnitee as a result of, or arising out of, or relating to (a) any misrepresentation or breach of any representation or warranty made by the Company or any of the Guarantors in the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby, (b) any breach of any covenant, agreement or obligation of the Company or any of the Guarantors contained in the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby or (c) any cause of action, suit, or claim brought or made against such Indemnitee by a third party (including for these purposes a derivative action brought on behalf of the Company or any Guarantor) and arising out of or resulting from (i) the execution, delivery, performance or enforcement of the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby, (ii) any transaction financed or to be financed in whole or in part, directly or indirectly, with the proceeds of the Transactions, or (iii) the status of such Investor as an investor in the Company or a Guarantor pursuant to the Transactions or any other transactions contemplated by the Transaction Documents and the transactions contemplated hereby and thereby; in each of the foregoing cases other than Indemnified Liabilities (x) resulting from a claim solely among the Indemnitees, and (y) with respect to an individual Investor, to the extent finally determined by a court of competent jurisdiction to have resulted from (i) the bad faith, gross negligence or willful misconduct of such Indemnitee, or (ii) a material breach by such Investor of its obligations under this Agreement. To the extent that the foregoing undertaking by the Company and the Guarantors may be unenforceable for any reason, the Company and the Guarantors, jointly and severally, shall make the maximum contribution to the payment and satisfaction of each of the Indemnified Liabilities that is permissible under applicable law.

13. Indemnification Procedures. Promptly after receipt by an Indemnitee of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under Section 12, notify the indemnifying party in writing of the commencement thereof; but the failure so to notify the indemnifying party (i) will not relieve it from liability under Section 12 unless and to the extent such failure results in the forfeiture by the indemnifying party of substantial rights and defenses and (ii) will not, in any event, relieve the indemnifying party from any obligations to any Indemnitee other than the indemnification obligation provided in Section 12. The indemnifying party shall be entitled to appoint counsel of the indemnifying party's choice at the indemnifying party's expense to represent the Indemnitee in any action for which indemnification is sought (in which case the indemnifying party shall not thereafter be responsible for the fees and expenses of any separate counsel, retained by the Indemnitee or parties except as set forth below); *provided, however*, that such counsel shall be reasonably satisfactory to the Indemnitee. Notwithstanding the indemnifying party's election to appoint counsel to represent the Indemnitee in an action, the Indemnitee shall have the right to employ one separate counsel (in addition to one local counsel in each applicable jurisdiction, if needed), and the indemnifying party shall bear the reasonable fees, costs and expenses of such separate counsel, if (i) the use of counsel chosen by the indemnifying party to represent the Indemnitee would present such counsel with a conflict of interest; (ii) the actual or potential defendants in, or targets of, any such action include both the Indemnitee and the indemnifying party and the Indemnitee shall have reasonably concluded that there may be legal defenses available to it and/or other Indemnitees that are different from or additional to those available to the indemnifying party; (iii) the indemnifying party shall not have employed counsel reasonably satisfactory to the Indemnitee to represent the Indemnitee within a reasonable time after notice of

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the institution of such action; or (iv) the indemnifying party shall not be authorized to employ separate counsel at the expense of the indemnifying party. An indemnifying party will not, without the prior written consent of the Indemnitees, settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the Indemnitees are actual or potential parties to such claim or action) unless such settlement, compromise or consent includes an unconditional release of each Indemnitee from all liability arising out of such claim, action, suit or proceeding and does not include any admission as to fault, culpability or failure to act on the part of any Indemnitee.

14. Termination. In the event that the Transactions shall not have occurred with respect to an Investor on or before March 7, 2023 due to the Company's or such Investor's failure to satisfy any of the conditions required to be satisfied by it in Section 9 (and the nonbreaching party's failure to waive such unsatisfied condition(s)), the nonbreaching party shall have the option to terminate this Agreement with respect to such breaching party at the close of business on such date without liability of any party to any other party; provided, however, that the Company's obligations under Sections 8(e) and Section 11 to the other party shall survive any such termination. This Agreement may be terminated in the absolute discretion of each of the Investors and as to such Investor on an individual basis, by notice to the Company, if after the execution and delivery of this Agreement and on or prior to the Closing Date (i) trading generally shall have been suspended or materially limited on the Principal Market or the over-the-counter market; (ii) trading of any securities issued or guaranteed by the Company or any of the Guarantors shall have been suspended on any exchange or in any over-the-counter market; (iii) a general moratorium on commercial banking activities shall have been declared by federal or New York State authorities; or (iv) there shall have occurred any outbreak or escalation of hostilities or any change in financial markets or any calamity or crisis, either within or outside the United States, that, in the good faith judgment of such Investor, is material and adverse and makes it impracticable or inadvisable to proceed with the Transactions on the terms and in the manner contemplated by this Agreement. [Notwithstanding anything to the contrary contained herein or in any Other Agreement, in the event of a termination of this Agreement in accordance with this Section 14, each Other Agreement shall automatically terminate.]

15. Nature of Obligations and Rights of Investors.

(a) The respective obligations of each Investor and each Other Investor, as applicable, under this Agreement and each Other Agreement, as applicable, and the Transaction Documents are several and not joint with the obligations of any other Investor or any Other Investor, as applicable, and no Investor or Other Investor, as applicable, shall be responsible in any way for the performance of the obligations of any other Investor or Other Investor, as applicable, under this Agreement or any Other Agreement, as applicable, or the other Transaction Documents. The failure or waiver of performance under this Agreement or any Other Agreement, as applicable, by any Investor or any Other Investor, as applicable, or on its or their own behalf, as applicable, does not excuse performance by any other Investor or any Other Investor, as applicable. Nothing contained herein or in any other Transaction Document, and no action taken by any Investor or Other Investor, as applicable, pursuant thereto, shall be deemed to constitute the Investors or Other Investors, as applicable, as a partnership, an association, a joint venture or any other kind of entity,

or create a presumption that the Investors or Other Investor are acting in concert or as a group with respect to such obligations or any of the Transactions or any other transactions contemplated by the Transaction Documents. Except as otherwise provided in the Transaction Documents, each Investor and each Other Investor, as applicable, shall be entitled to independently protect and enforce its rights, including the rights arising out of the Transaction Documents, and it shall not be necessary for any other Investor or Other Investor, as applicable, to be joined as an additional party in any proceeding for such purpose. The decision of each Investor or Other Investor, as applicable, to acquire the New Securities in connection with the Transactions has been made by such Investor or such Other Investor, as applicable, independently of any other Investor or Other Investor, as applicable. Each Investor and each Other Investor acknowledges that no other Investor or Other Investor, as applicable, has acted as agent for such Investor or Other Investor, as applicable, in connection with making its investment hereunder and that no Investor or Other Investor, as applicable, will be acting as agent of such Investor or Other Investor, as applicable, in connection with monitoring its investment in the New Securities, or enforcing its rights under this Agreement or any Other Agreement, as applicable, or any other Transaction Document. The Company acknowledges that each of the Investors and each of the Other Investors, as applicable, has been provided with the same New Notes Indenture (and Warrant provided therein) for the purpose of closing a transaction with multiple Investors and Other Investors and not because it was required or requested to do so by any Investor or Other Investor, as applicable.

(b) The Company acknowledges and agrees that (a) each Investor is acting at arm's length from each other Investor with respect to this Agreement and the other Transaction Documents and the transactions contemplated hereby and thereby; (b) no Investor will, by virtue of this Agreement or any of the other Transaction Documents or any transaction contemplated hereby or thereby, be or otherwise is an Affiliate of, or have any agency, tenancy or joint venture relationship with, the Company; (c) no Investor has not acted, or is or will be acting, as a financial advisor to, or fiduciary (or in any similar capacity) of, or has any fiduciary or similar duty to, the Company with respect to, or in connection with, this Agreement and the other Transaction Documents and the transactions contemplated hereby and thereby, and the Company agrees not to assert, and hereby waives, to the fullest extent permitted under Applicable Law, any claim that any Investor has any fiduciary duty to the Company; (d) any advice given by an Investor or any of its representatives or agents in connection with this Agreement and the other Transaction Documents and the transactions contemplated hereby and thereby is merely incidental to such Investor's performance of its obligations hereunder and thereunder (including, in the case of each of the Investors, its acquisition of the Securities); and (e) the Company's decision to enter into the Transaction Documents has been based solely on the independent evaluation by the Company and its representatives.

(c) The Company acknowledges and agrees that none of the Investors or holders of the Securities has been asked to agree, nor has any Investor agreed, to desist from purchasing or selling, long and/or short, Stock or other securities of the Company, or "derivative" securities or Stock based on Stock or other securities issued by the Company or to hold the Securities for any specified term; and no Investor nor holder of Securities shall be deemed to have any affiliation with or control over any arm's length counterparty

in any "derivative" transaction. The Company further agrees that one or more Investors or holders of Securities may engage in hedging and/or trading activities at various times during the period that the Securities are outstanding, (b) such hedging and/or trading activities, if any, can reduce the value of the shares of Common Stock or other Stock held by the existing holders of shares of Common Stock or other Stock of the Company, both at and after the time the hedging and/or trading activities are being conducted; (c) any such hedging and/or trading activities shall not constitute a breach of any Transaction Document or affect any of the rights of any Investor or holder of Securities under any Transaction Document; (d) the issuance of any Conversion Shares may result in dilution of the outstanding shares of Common Stock, which dilution may be substantial under certain market conditions; and (e) the Obligations, including the Company's obligation to issue the Conversion Shares upon conversion of the New Notes and Warrant Shares upon exercise of the Warrants, are unconditional and absolute and not subject to any right of set off, counterclaim, delay or reduction, regardless of the effect of any such dilution or any claim the Company or any of its Subsidiaries may have against any of the Investors and regardless of the dilutive effect that such issuance may have on the ownership of the other stockholders of the Company.

16. Further Assurances. Each of the parties hereto hereby agrees: (i) that it shall use its commercially reasonable best efforts to timely satisfy each of the conditions to be satisfied by it as provided in Sections 9 of this Agreement, and (ii) from time to time, as and when reasonably requested by any other party hereto, to execute and deliver or cause to be executed and delivered, all such documents, instruments and agreements, including secretary's certificates, stock powers and irrevocable transfer agent instructions, and to take or cause to be taken such further or other action, as may be reasonably necessary or desirable in order to carry out the intent and purposes of this Agreement.

17. Survival Clause. The respective representations, warranties, agreements and other statements of the Company and the Investors set forth in this Agreement shall remain in full force and effect, regardless of delivery of and payment for the New Notes and New Shares, provided that representations and warranties made as of the date hereof, as of the Closing Date, and/or other specific dates shall speak solely as of those date(s). The respective indemnities provided in Section 12 and reimbursement provisions in Section 11 shall also remain in full force and effect following the delivery of the Securities.

18. Notices. Any notice, request, instruction or other document to be given hereunder by any party to the other will be in writing and will be deemed to have been duly given (a) on the date of delivery if delivered personally or by electronic mail (so long as such transmission does not generate an error message or notice of non-delivery), (b) on the first business day following the date of dispatch if delivered by a recognized next-day courier service, or (c) on the third business day following the date of mailing if delivered by registered or certified mail, return receipt requested, postage prepaid. All communications hereunder, if sent to any of the Investors, shall be delivered to each Investor in accordance with each Investor's Investor Information Form, substantially in the form set forth in Exhibit A-5 hereto, as the same may be updated by each Investor from time to time by notice to the Company in accordance with this Section 18 and with a copy to Outside Counsel listed on the signature page hereto; and if sent to the Company, shall be mailed or delivered to the Company at:

Invitae Corporation

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1400 16th Street, San Francisco, California, 94103

Attention: General Counsel

Email: *****

With a copy to:

Latham & Watkins LLP

200 Clarendon Street

Boston, MA 02116

Attention: Wesley Holmes; Reza Mojtabae-Zamani

Email: Wesley.Holmes@LW.com; Reza.Mojtabae-Zamani@lw.com

In addition to any other notice required to be given to any of the Deerfield Holders hereunder or pursuant to any of the other Transaction Documents, subject to Section 8(e), the Company shall cause any notice required to be delivered to the Trustee under the New Notes Indenture pursuant to Section 4.18 of the New Notes Indenture to each Deerfield Holder substantially contemporaneously with the delivery thereof to the Trustee.

19. Successors and Third Parties. All of the covenants and provisions of this Agreement by or for the benefit of the any of the Investors or the Company and the Guarantors shall bind and inure to the benefit of their respective successors and permitted assigns. No party hereunder may assign its rights or obligations hereunder without, in the case of any Investor, the consent of the Company, and in the case of the Company, the consent of each of the Investors, except that each Investor may, without the consent of the Company, assign its rights hereunder to any Related Fund (as defined below) of such Investor and/or to any assignee or transferee of the Securities; provided, that no such assignment shall relieve such Investor of its obligations hereunder. "**Related Fund**" of any Investor means any investment fund or managed account that is managed on a discretionary basis by the same investment manager as such Investor. Notwithstanding the foregoing, upon any assignment, sale, or other disposition of the Securities, each subsequent holder of such Securities shall be entitled to, and shall be entitled to enforce, any rights and benefits hereunder applicable to such Securities as if such holder had been an Investor hereunder.

20. Applicable Law. This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or related to this Agreement, or the negotiation, execution or performance of this Agreement (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by, and enforced in accordance with, the internal laws of the State of New York, including its statutes of limitations. Each of the Company, the Guarantors and the Investors hereby irrevocably submits to the exclusive jurisdiction of the federal and state courts sitting in the Borough of Manhattan in the City of New York in respect of any suit, action or proceeding arising out of or relating to this Agreement, the Transactions or, except as otherwise provided in any of the other Transaction Documents, the Securities, and irrevocably accepts for itself and in respect of its property, generally and unconditionally, jurisdiction of the aforesaid courts.

21. WAIVER OF JURY TRIAL. EACH OF THE COMPANY AND THE INVESTORS IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY WITH RESPECT TO ANY LEGAL PROCEEDING ARISING OUT OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT.

22. Entire Agreement. This Agreement, together with the other Transaction Documents, constitutes the entire agreement, and supersedes all other prior and contemporaneous agreements and understandings, both oral and written, among the Investors and the Company and the Guarantors with respect to the subject matter hereof.

23. Amendments and Waivers. No provision of this Agreement may be waived or amended except in a written instrument signed by the Company and each affected Investor [and no provision of any Other Agreement may be directly or indirectly waived, amended or otherwise modified without the written consent of the Deerfield Holders]. No waiver of any breach or default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent breach or default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

24. Severability. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.

25. Headings. The headings herein are included for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement.

26. Miscellaneous. This Agreement may be executed in counterparts, and delivered by email or facsimile, each of which shall be deemed an original, but all of which shall constitute one and the same instrument. Delivery of an executed signature page of this Agreement by e-mail, facsimile or other transmission (e.g., "pdf" format) shall be effective as delivery of a manually executed counterpart hereof. Each party agrees that this Agreement and any other documents to be delivered in connection herewith may be electronically signed, and that any electronic signatures appearing on this Agreement or such other documents shall have the same legal validity and enforceability as a manually executed signature or use of a paper-based recordkeeping system to the fullest extent permitted by applicable law, including the Federal Electronic Signatures in Global and National Commerce Act and the New York State Electronic Signatures and Records Act.

27. No Strict Construction; Rules of Construction. The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent, and no rule of strict construction will be applied against any party. Unless the context otherwise requires, (i) all references to Sections, Schedules or Exhibits are to Sections, Schedules or Exhibits contained in or attached to this Agreement, (ii) words in the singular or plural include the singular and plural, and pronouns stated in either the masculine, the feminine or neuter gender shall include the masculine, feminine and neuter, (iii) the use of the word "include", "includes" and "including" in this Agreement shall be by way of example rather than limitation, and (iv) the word "or" is not exclusive (i.e., "or" shall mean "and/or").

28. Third-Party Beneficiaries. The Financial Advisors and third parties rely on the representations and warranties of the Company and the Guarantors in subsection 6 and the representations and warranties of the Investor in [subsections 7(k), 7(l), 7(o), 7(q) and 7(s)][Section 7] of this Agreement. The Financial Advisors may rely on each representation and warranty of the Company and the Investors in the subsections specified in the immediately preceding sentence [made herein or pursuant to the terms hereof with the same force and effect] as if such representation or warranty were made directly to the Financial Advisors. [This Agreement is intended for the benefit of the parties hereto and the Financial Advisors and their permitted successors and assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other person, except as otherwise set forth in this Section 28.]

[Signature Page Follows]

INVITAE CORPORATION

By: _____
Name:
Title:

[GUARANTOR]

By: _____
Name:
Title:

[Signature Page to Purchase and Exchange Agreement]

AGREED AND ACCEPTED:

By: _____
Print Name: _____
Title: _____

-

Legal Counsel:

[Signature Page to Purchase and Exchange Agreement]

EXHIBIT 48

**AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
INVITAE CORPORATION**

Invitae Corporation, a corporation organized and existing under the laws of the State of Delaware, hereby certifies as follows:

FIRST: The name of the corporation is Invitae Corporation

SECOND: The original Certificate of Incorporation of the corporation was filed with the Secretary of State of the State of Delaware on January 13, 2010, under its former name “Locus Development, Inc.”

THIRD: The Certificate of Incorporation of the corporation was most recently amended and restated pursuant to an Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on October 7, 2014, and is hereby further amended and restated pursuant to Sections 242 and 245 of the General Corporation Law of the State of Delaware.

FOURTH: The Certificate of Incorporation of the corporation shall be amended and restated to read in full as follows:

ARTICLE I

The name of the Corporation is Invitae Corporation (the “*Corporation*”).

ARTICLE II

The address of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, Wilmington, County of New Castle, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the Delaware General Corporation Law (the “*DGCL*”).

ARTICLE IV

A. Classes of Stock. The total number of shares of all classes of capital stock that the Corporation shall have authority to issue is Four Hundred Twenty Million (420,000,000), of which Four Hundred Million (400,000,000) shares shall be Common Stock, \$0.0001 par value per share (the “*Common Stock*”), and of which Twenty Million (20,000,000) shares shall be Preferred Stock, \$0.0001 par value per share (the “*Preferred Stock*”). The number of authorized shares of Common Stock or Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of

a majority of the then outstanding shares of Common Stock, without a vote of the holders of the Preferred Stock, or of any series thereof, unless a vote of any such Preferred Stock holders is required pursuant to the provisions established by the Board of Directors of the Corporation (the “*Board of Directors*”) in the resolution or resolutions providing for the issue of such Preferred Stock, and if such holders of such Preferred Stock are so entitled to vote thereon, then, except as may otherwise be set forth in the certificate of incorporation of the Corporation, the only stockholder approval required shall be the affirmative vote of a majority of the voting power of the Common Stock and the Preferred Stock so entitled to vote, voting together as a single class.

B. Preferred Stock. The Preferred Stock may be issued from time to time in one or more series, as determined by the Board of Directors. The Board of Directors is expressly authorized to provide for the issue, in one or more series, of all or any of the remaining shares of Preferred Stock and, in the resolution or resolutions providing for such issue, to establish for each such series the number of its shares, the voting powers, full or limited, of the shares of such series, or that such shares shall have no voting powers, and the designations, preferences and relative, participating, optional or other special rights of the shares of such series, and the qualifications, limitations or restrictions thereof. The Board of Directors is also expressly authorized (unless forbidden in the resolution or resolutions providing for such issue) to increase or decrease (but not below the number of shares of such series then outstanding) the

number of shares of any series subsequent to the issuance of shares of that series. In case the number of shares of any such series shall be so decreased, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

C. Common Stock.

1. Relative Rights of Preferred Stock and Common Stock. All preferences, voting powers, relative, participating, optional or other special rights and privileges, and qualifications, limitations, or restrictions of the Common Stock are expressly made subject and subordinate to those that may be fixed with respect to any shares of the Preferred Stock.

2. Voting Rights. Except as otherwise required by law or the certificate of incorporation of the Corporation, each holder of Common Stock shall have one vote in respect of each share of stock held by such holder of record on the books of the Corporation for the election of directors and on all matters submitted to a vote of stockholders of the Corporation.

3. Dividends. Subject to the preferential rights of the Preferred Stock, the holders of shares of Common Stock shall be entitled to receive, when, as and if declared by the Board of Directors, out of the assets of the Corporation which are by law available therefor, dividends payable either in cash, in property or in shares of capital stock.

4. Dissolution, Liquidation or Winding Up. In the event of any dissolution, liquidation or winding up of the affairs of the Corporation, after distribution in full of the preferential amounts, if any, to be distributed to the holders of shares of the Preferred Stock, holders of Common Stock shall be entitled, unless otherwise provided by law or the certificate of incorporation of the Corporation, to receive all of the remaining assets of the Corporation of

whatever kind available for distribution to stockholders ratably in proportion to the number of shares of Common Stock held by them respectively.

ARTICLE V

In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware:

A. The Board of Directors is expressly authorized to adopt, amend or repeal the bylaws of the Corporation, without any action on the part of the stockholders, by the vote of at least a majority of the directors of the Corporation then in office. In addition to any vote of the holders of any class or series of stock of the Corporation required by law or the certificate of incorporation of the Corporation, the bylaws may also be adopted, amended or repealed by the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of the shares of the capital stock of the Corporation entitled to vote in the election of directors, voting as one class; provided, however, that the affirmative vote of the holders representing only a majority of the voting power of the shares of the capital stock of the Corporation entitled to vote in the election of directors, voting as one class, shall be required if such adoption, amendment or repeal of the bylaws has been previously approved by the affirmative vote of at least two-thirds (2/3) of the directors of the Corporation then in office.

B. Elections of directors need not be by written ballot unless the bylaws of the Corporation shall so provide.

C. The books of the Corporation may be kept at such place within or without the State of Delaware as the bylaws of the Corporation may provide or as may be designated from time to time by the Board of Directors.

ARTICLE VI

A. The business and affairs of the Corporation shall be managed by a Board of Directors. The authorized number of directors of the Corporation shall be fixed in the manner provided in the bylaws of the Corporation. Other than for those directors elected by the holders of any series of Preferred Stock, which shall be as provided for or fixed pursuant to the provisions of Article IV, Paragraph B hereof, each director shall serve until his or her successor shall be duly elected and qualified or until his or her earlier resignation, removal from office, death or incapacity.

B. Subject to the rights of the holders of any series of Preferred Stock then outstanding, newly created directorships resulting from any increase in the authorized number of directors or any vacancies in the Board of Directors resulting from death, resignation, retirement, disqualification, removal from office or other cause shall be filled solely by a majority vote of the directors then in office, although less than a quorum, or by a sole remaining director. If there are no directors in office, then an election of directors

may be held in the manner provided by statute. Directors chosen pursuant to any of the foregoing provisions shall hold office until their successors are duly elected and qualified or until their earlier resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of

any incumbent director. In the event of a vacancy in the Board of Directors, the remaining directors, except as otherwise provided by law, or by the certificate of incorporation or the bylaws of the corporation, may exercise the powers of the full Board of Directors until the vacancy is filled.

ARTICLE VII

- A. No action required or permitted to be taken at any annual or special meeting of the stockholders may be taken without a meeting and the power of stockholders to consent in writing, without a meeting, to the taking of any action is specifically denied.
- B. Special meetings of the stockholders of the Corporation may be called only by the Chairman of the Board of Directors or the Chief Executive Officer of the Corporation or by a resolution adopted by the affirmative vote of a majority of the Board of Directors, and any power of stockholders to call a special meeting of stockholders is specifically denied.
- C. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner and to the extent provided in the bylaws of the Corporation.
- D. Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, or (iv) any action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article VII, Paragraph D.

ARTICLE VIII

- A. Limitation on Liability. To the fullest extent permitted by the DGCL, as the same exists or as may hereafter be amended (including, but not limited to Section 102(b)(7) of the DGCL), a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL hereafter is amended to further eliminate or limit the liability of directors, then the liability of a director of the Corporation, in addition to the limitation on personal liability provided herein, shall be limited to the fullest extent permitted by the amended DGCL. Any repeal or modification of this paragraph by the stockholders of the Corporation shall be prospective only, and shall not adversely affect any limitation on the personal liability of a director of the Corporation existing at the time of such repeal or modification.
- B. Indemnification. Each person who is or was a director or officer of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, employee benefit plan or other enterprise (including the heirs, executors, administrators or estate of such

person), shall be indemnified and advanced expenses by the Corporation, in accordance with the bylaws of the Corporation, to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than said law permitted the Corporation to provide prior to such amendment), or any other applicable laws as presently or hereinafter in effect. The right to indemnification and advancement of expenses hereunder shall not be exclusive of any other right that any person may have or hereafter acquire under any statute, provision of the certificate of incorporation or bylaws of the Corporation, agreement, vote of stockholders or disinterested directors or otherwise.

C. Insurance. The Corporation may, to the fullest extent permitted by law, purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise against any expense, liability or loss incurred by such person in any such capacity or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

D. Repeal and Modification. Any repeal or modification of the foregoing provisions of this Article VIII shall not adversely affect any right or protection existing hereunder immediately prior to such repeal or modification.

ARTICLE IX

The affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of the shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend in any respect or repeal this Article IX, Paragraph A of Article V, or Articles VI, VII or VIII.

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IN WITNESS WHEREOF, the corporation has caused this certificate to be signed by its Chief Executive Officer this 18th day of February, 2015.

INVITAE CORPORATION

By /s/ Randal W. Scott

Randal W. Scott, Chief Executive Officer

EXHIBIT 49

Industry Update — October 15, 2021

Life Science Tools, Services, & Diagnostics

Plenty Is Never Enough: Tools, EDx Tough; CROs Safer?

Our Call

Bottom Line: We see a tough setup in Q3 for our Life Science Tools, Services, and Diagnostics coverage. While investors have enjoyed big core beats over the past 3 quarters, expectations have risen accordingly and upside is mathematically more challenged. COVID testing has returned, but we don't expect investors will pay for COVID testing upside. Doc office access remains restricted, a headwind for promotionally sensitive diagnostics. We continue to favor Tools & Services with outsized biopharma exposure as a theme. Our top large cap picks heading into earnings are Bio-Rad (BIO - margin expansion, product cycle, derivative bioprocess exposure), Hologic (HOLX - faster post-pandemic growth), and IQVIA (IQV - TAM expansion + strong clinical trial trends). In emerging growth diagnostics, our favorites are Natera (NTRA - execution + catalyst path) and Guardant Health (GH - catalyst path).

Tools are tough. Avantor's (AVTR) -8% stock reaction on its sales preannouncement crystallized our concerns on Tools more broadly into this earnings season. Expectations have reset to a higher level and core growth beats should be narrower. Core misses (ex COVID testing) will get punished. To boot, we'll likely hear cautious Q4 commentary from Tools vendors comp'ing what appeared to be a substantial budget flush in Q4 2020. All that said, we believe the AVTR reaction overdone and consider the sell-off a good buying opportunity. The eventual core sales disclosure could surprise to the upside while forthcoming consolidation provides an EPS tailwind. Relative to the broader market, Tools valuations are back in their normal range (~1.4-1.6x SP500 FY2 EV/EBITDA) but at the high end at 1.6x. Not cheap, even after the group sell-off we've seen over the past month.

China to remain a concern for investors. Tools are uniquely exposed to China within healthcare, exposure that has historically been a source of relative strength. Now, investors are increasingly worried about demand trends in China. In fact, we found a document this week outlining local sourcing requirements for analytical instruments by government health entities (discussed herein, pdf available on request). We remain positive on China ([here](#)), but no longer expect a rising tide to lift all boats equally.

Emerging growth diagnostics (EDx) dogged by doc office access challenges. Rising interest rates and the growth to value rotation are especially unfriendly to emerging growth diagnostics stocks. Further, physician office access to sales reps remains constrained (Exhibit 21-22 herein), a challenge for companies that sell promotionally sensitive products. We believe these constraints will challenge any sales upside for the emerging growth diagnostics group this earnings season. Attention will be focused on the catalyst paths for the various companies.

CROs the "safe haven"? While CROs aren't immune to pandemic related challenges and the clinical trial environment is not yet normalized, most demand signals are positive, and we see multiple avenues for these companies to create value ([here](#)). Moreover, the 2nd largest CRO already messaged guidance towards the high end of its range at an investor conference in mid-Sept, a positive signal for the operating environment. Valuations on CROs remain more reasonable as well, trading within their historical relative valuation band [1.2x S&P500 (typical band of 1.1-1.3x)].

Holistic view of Hologic. While we don't believe HOLX investors will get paid for a big COVID testing beat, we do think normalization in core diagnostics volume should enable HOLX's core growth in aggregate to compare favorably vs medical device peers'.

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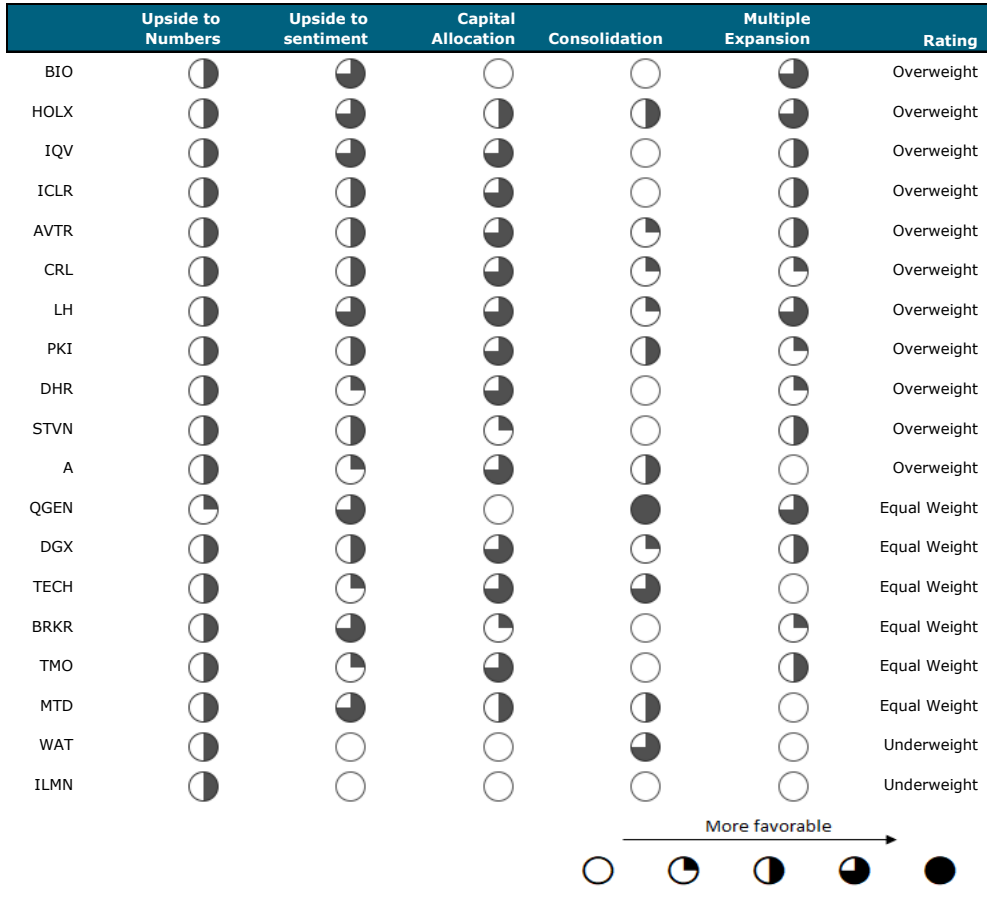
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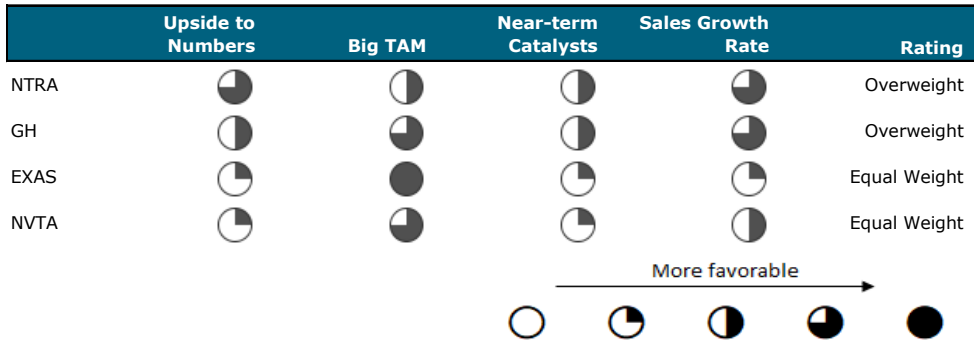
Part I. Pre-Q Stock Selection Framework

Tools, Services & Diagnostics



Source: Wells Fargo Securities, LLC estimates

Emerging Growth Diagnostics



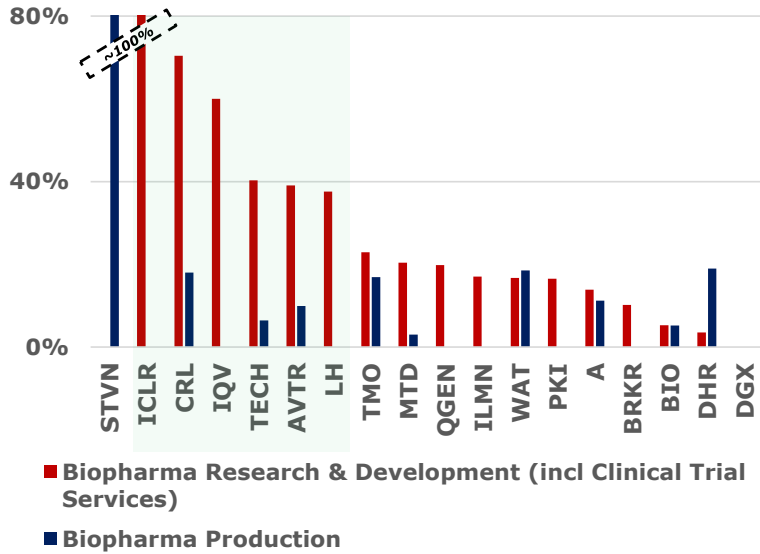
Source: Wells Fargo Securities, LLC estimates

CRO's provide exposure to high growth end markets (Biopharma) without as much supply chain risk

Of our coverage the names with the greatest exposure to Biopharma Research & Development include ICLR, CRL, IQV, TECH, AVTR and LH. Of the Pharma Services names we cover (CROs and Labs) ICLR and CRL are most exposed and of our Tools/Dx names TECH and AVTR are most exposed.

Exhibit 1: Biopharma Exposure by Coverage Company - Research & Development vs. Production

Biopharma Exposure (% of FY20 Sales) by R&D vs. Production



Source: Wells Fargo Securities, LLC estimates, company reports
 Note: Reflects FY20 organic exposure, not including 2H20/21 M&A

Part II. End Market Heat Map

Life Science Tools, Services and Diagnostics companies have a wide range of end market exposures in various regions, in which identifying who is best exposed to high-quality growth factors is a key strategy investors use to differentiate company specific outlooks in the space.

Exhibit 2: Heat Map Discussion Summary

END MARKET TRENDS WORSENING BUT PHARMA/BIOTECH REMAINS THE STANDOUT			
End Market	Trend	Commentary	Stocks
Pharma / Biotech		Positive momentum support market growth, bioproduction may be too hot - Bioproduction stands out and core business continues to recover; rising supply chain risk on top of existing pockets of - Non-COVID clinical trial activities improve; strong pipeline - Biopharma funding in YTD'21 still strong vs. last year, even without 4Q21 the '20+YTD21 funding still >50% above prior record - '18+'19 years; capital market environment getting more cautious - FDA remains accommodative, biopharma pipelines swelling	WAT, AVTR, TECH, TMO, IQV, CRL, ICLR
Applied / Industrial		Turning over after ramp from lows to multi-year highs - Macro environment has changed since earnings commentary expecting continued recovery in Q3; previous commentary flagging supply constraints and cost pressures as manageable no longer comparable - US and EU PMIs rolling over off of multi-year highs; capex outlook moderating but still positive - Labor shortages and wage inflation in unskilled labor worse than semi-skilled / skilled labor	MTD, A, DHR, PKI, AVTR, BRKR
Clinical / Diagnostics		Mixed trends driven by COVID dynamics, COVID driven guidance upside likely to continue - Routine testing / patient visits improved in Q3, moving closer to pre-COVID level - COVID PCR test shipments in Q3 were nearly double Q2 and nearly on par with Q1, upsides to FY guide likely on COVID tailwinds	DGX, LH, BIO, QGEN, PKI, DHR
Aca / Gov't		Returned to growth, favorable funding environment but near-term risks rising - Academic labs still below full capacity, continue progress reopening but slower than expected - Management expectations are for sequential FY21 improvement; recent updates risk to reopening tailwind - Strong funding environment globally, strong focus in healthcare development; rising political risk - Recent checks and management commentary (Sept. confrences) flag slower than expected recovery in lab activity	BRKR, TECH, BIO, QGEN, TMO, AVTR

Source: Wells Fargo Securities, LLC

REGIONAL GROWTH TRENDS MIXED WITH COVID AND SUPPLY CHAIN IMPACTS			
Geography	Trend	Commentary	Stocks
US		Recovery and COVID tailwinds contributing growth but fading; deficit spending a benefit but DC is noisy - Strong growth momentum continued through the end of Q3 but recent macro environment has worsened - PMIs turning over from multi-year highs; Unemployment rate falling but volatile - Strong funding environment, accommodating FDA, biopharma pipelines swelling; capital market environment turning cautious - Rising macro headwinds from input cost inflation and supply chain disruptions; US political risk rising	AVTR, TECH, TMO, GGEN BIO
Europe		Recovery continues but energy and supply chain a growing factor - Core business recovery continued in Q3, strong COVID testing demand - Favorable funding environment with Horizon Europe 2021-2027 budget totaling €95.5bn; initial FY22 budget proposed 6% increase in funding - European PMIs turning over with worsening macro environment - Rising macro headwinds from input cost inflation and supply chain disruptions; Energy concerns rising	AVTR, BIO, BRKR, MTD QGEN, TECH
China		Long-term growth led by Biopharma; Weaker factory activities near-term - Broad-based improvement with Biopharma leading the growth continued in Q3 - Sept manufacturing PMIs showed contraction in factory activities and supply constraints; expect the weak economic activities to continue in near-term due to electricity shortage, supply constraints and etc. - Total gov't funding increases 3.3% in FY21, focus on basic science research (central gov't funding +10.6%) - We believe mid-term demand drivers are durable, but near-term supply chain/input cost risks	A, PKI, MTD, BRKR WAT, TMO, DHR, BIO

Source: Wells Fargo Securities, LLC

END MARKET TRENDS			
End Market	Trend	Commentary	Stocks
Oncology		Big TAMs with several credible multi-billion opportunities, although still early days - Testing volume expected to improve in Q3 - In-person sales reps visits slightly improved in August, led by +4% m/m increase in primary care in-person details, offsetting 3% m/m decline in oncology in-person details - GH initiates a 1,000-patient ORACLE study to evaluate Guardant Reveal (MRD) test across 11 solid tumors - Draft coverage for MRD testing likely to be finalized by year end; CMS finalized blood-based CRC screening coverage in Jan	EXAS, GH, NTRA, NVTA
Reproductive Health		Average-risk NIPT expansion - incremental volume and enhanced reimbursement - Testing volume expected to improve in Q3; still has room to grow ASP in 2H - PROG exited reproductive business, offers \$100M jump ball for NTRA, NVTA, LH - UnitedHealth average risk NIPT coverage went into effect Jan. 1 - NTRA expects to release its SMART study in 1H'22; potential guideline/reimbursement change in 2022-2023; - Any eventual guideline/reimbursement inclusion for microdeletions will be additional upside - NIPT ~35% penetrated in average-risk population by volume in the U.S., leaving room for meaningful additional market penetration	NTRA, NVTA
Genetics		Guideline expansion drives growth; pricing pressure likely continues - Testing volume expected to improve in Q3 - Guideline expansion drives growth in hereditary cancer market - Expect further cuts in key Medicare rates in 2022, pressure on reimbursement doesn't seem to be abating anytime soon	NVTA

Source: Wells Fargo Securities, LLC

China Update

We recently saw a document which outlines the instrument procurement standards for government health entities widely circulating online. The document lists the recommended mix of domestic products in the government's procurement purchases (in a range of 25% to 100%) for a total of 315 instruments across multiple industries/categories. Over 220 products are required to be sourced 100% domestically. We listed the relevant categories for our coverage in Exhibit 3. The list is the first detailed one that identifies what types of instruments and what percentage of the purchase are needed to be sourced locally. As we have recently written ([here](#)), this is another example to show the government's efforts in incentivizing localization and we expect the investors' concerns over regulatory changes will not go away anytime soon.

Exhibit 3: The Chinese government continues to push for localization to reduce dependency on global supply chain.

Gov't's Instrument Procurement Requirement for Selected Categories

# of products Category	Domestic products as % of total purchase				Total
	100%	75%	50%	25%	
Analytical instrument	32	5	5	25	67
Testing instrument	5	0	0	1	6
Clinical lab instrument	29	3	5	2	39

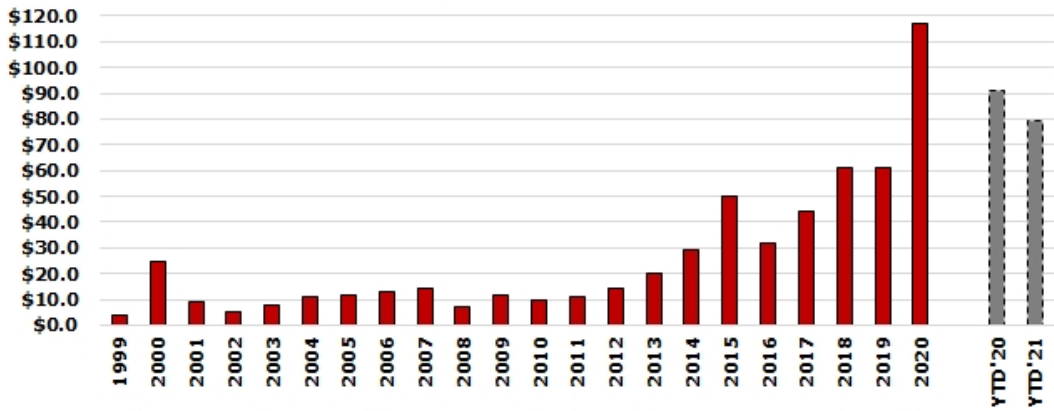
Source: Wells Fargo Securities, LLC

Pharma/Biotech End Market

While biopharma funding in YTD'21 is slower than last year, it remains at multi-year highs and saw a pick-up in Q3 (Exhibit 4). The capital market remains healthy with greater focus on public health and science research, supporting the future core growth in the Pharma/Biotech end market. Companies' intra-quarter commentaries reflected continued core business recovery and upside for COVID bioprocessing. COVID vaccine booster shot received limited recommendation in the US (currently only PFE/BNTX vaccine for people aged 65+, those at high risk of severe disease, and those at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting) and a broad endorsement in Europe. COVID vaccine/therapy tailwinds are likely to sustain longer due to the proliferation of new variants, vaccines for children and the strengthening case for boosters, which is consistent with increasing forecasts for vaccine sales at sponsor companies through 2022+ (Exhibit 5).

Exhibit 4: Biopharma funding level is lower than last year, but remains at multi-year highs.

BioPharma Equity Investments (venture, IPOs, follow-ons): Actual vs. 2020/21 YTD

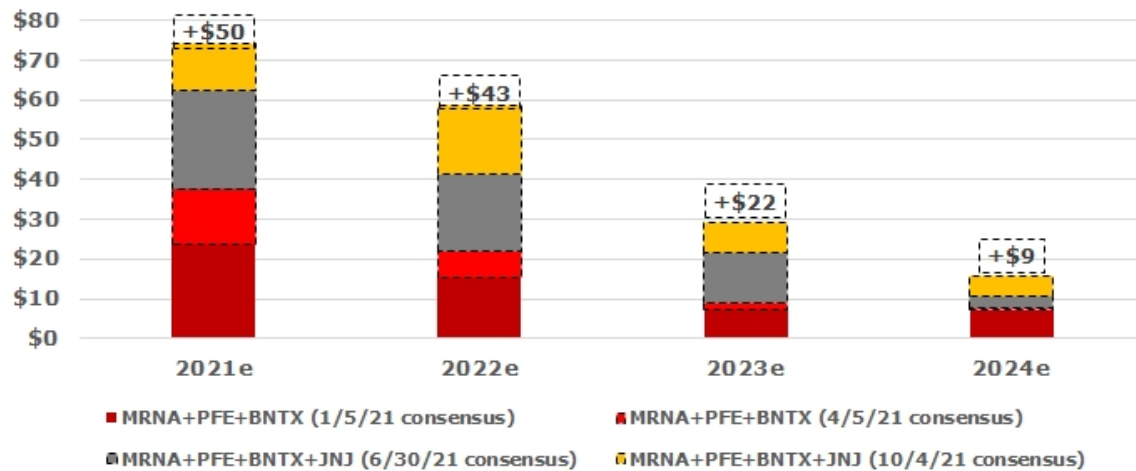


Note: Includes Venture, IPOs and follow-on; \$B: YTD 2020 and 2021 as of 10/11/21

Source: Wells Fargo Securities LLC, Biocentury

Exhibit 5: Vaccine tailwind forecasts have improved with variant proliferation and booster shots

Consensus Sales Forecast for Major COVID Vaccines (\$B): Start of 1Q21 vs. Current



Source: Wells Fargo Securities, LLC, Factset Estimates

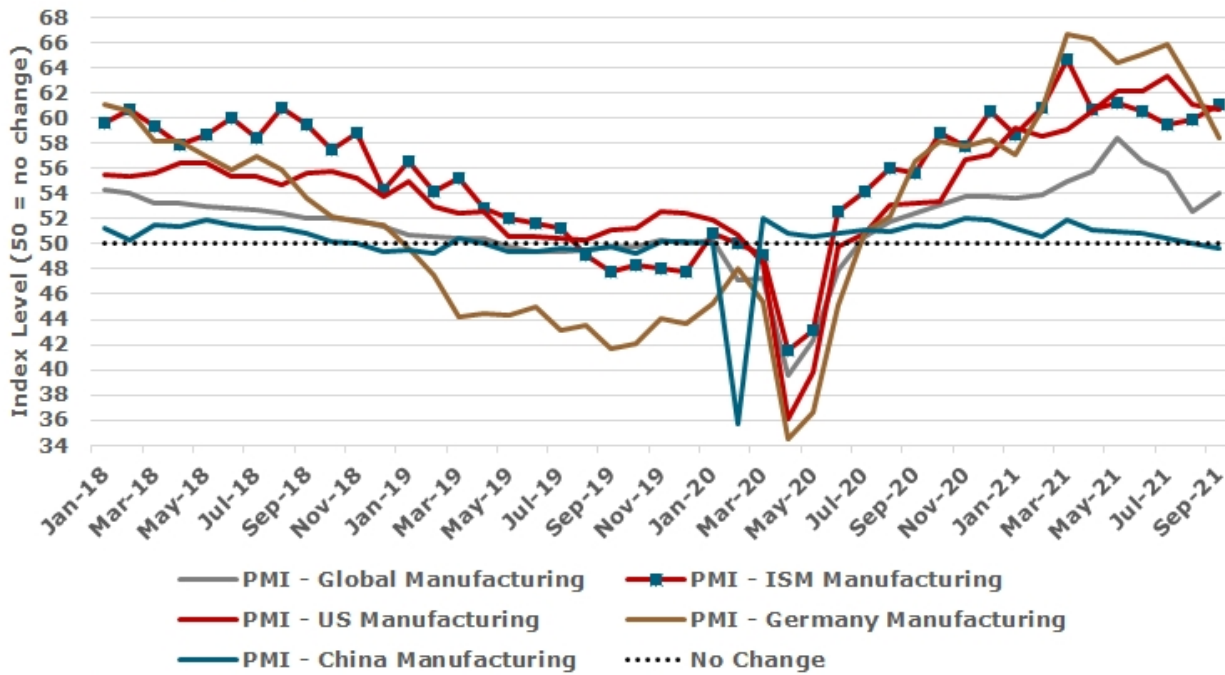
Note: Sum of product level revenue forecasts for each company. Consensus as of 1/5, 4/5, 6/30, 10/4/21.

Applied/Industrial End Market

The global manufacturing PMIs showed a mixed picture in September (Exhibit 6). Manufacturing production and new orders both rose in the month with European manufacturing dominated the growth. US manufacturing also performed strongly (Exhibit 8), while the weaker performances were generally seen in Asia. China saw contraction in the factory activities with manufacturing PMI of 49.6 vs. 50.1 in August. Meanwhile, supply constraints fed through to prices, leading to marked inflation of both input costs and factory gate selling prices (Exhibit 9). Tools companies within our coverage experienced various degrees of supply chain constraints but all expressed confidence in managing the risks.

Exhibit 6: September PMIs showed a mixed picture with growth expansion in Western regions and weaker performance in Asia

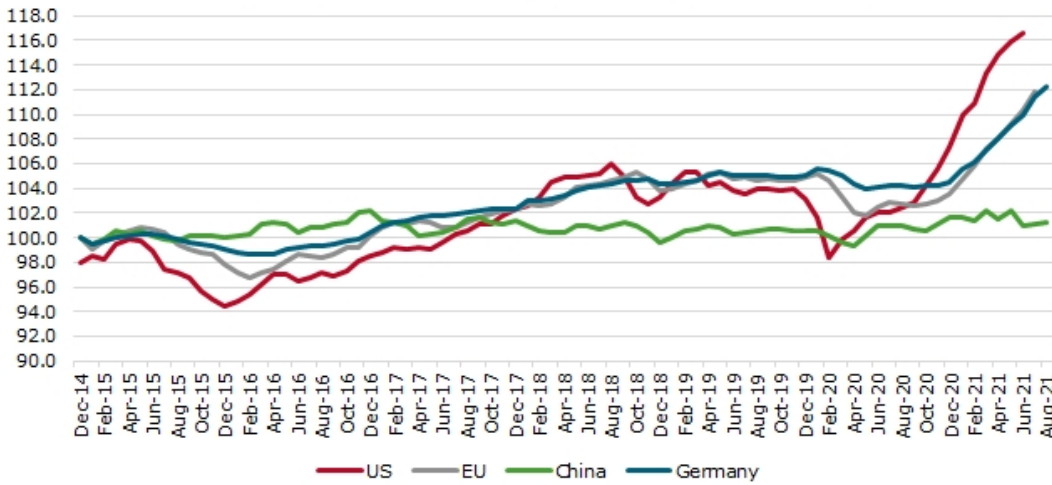
Manufacturing PMI: US, China, Germany & Global



Source: Wells Fargo Securities LLC, Bloomberg, Markit, JP Morgan, Institute for Supply Management

Exhibit 7: The manufacturing industries see rising cost inflationary pressures in raw materials and supply-chain disruptions

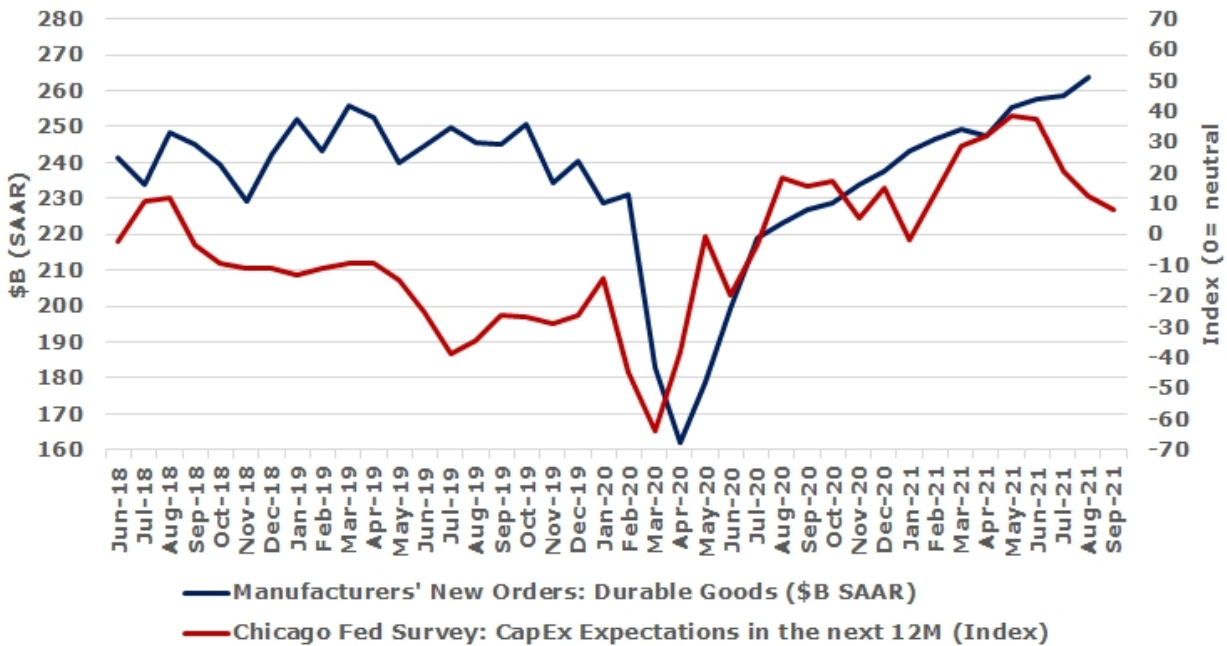
Producer Price Index (PPI): Total Manufacturing Industries (Dec 2014 = 100)



Source: Wells Fargo Securities, LLC; Federal Reserve Bank of St. Louis, OECD
China National Bureau of Statistics

Exhibit 8: Durable Goods Orders at multi-year highs, while CapEx outlook saw a slowdown

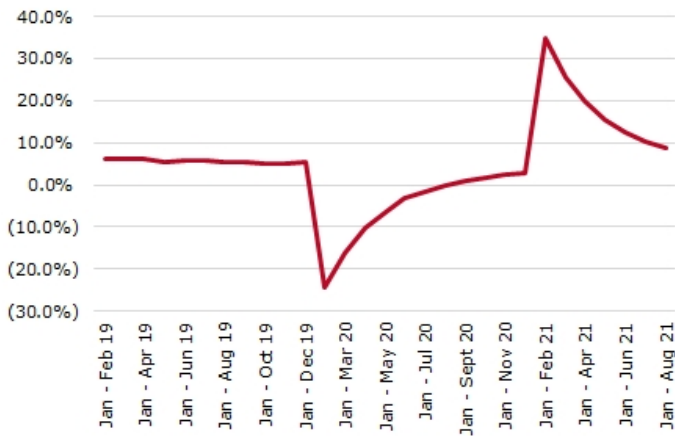
Industrial Manufacturing Orders vs. CapEx Outlook



Source: Wells Fargo Securities, LLC, Federal Reserve Bank of Chicago, U.S. Census

Exhibit 9 – 12: China Industrial production and fixed asset investment remain active in July/August

Fixed Asset Investment YoY Growth



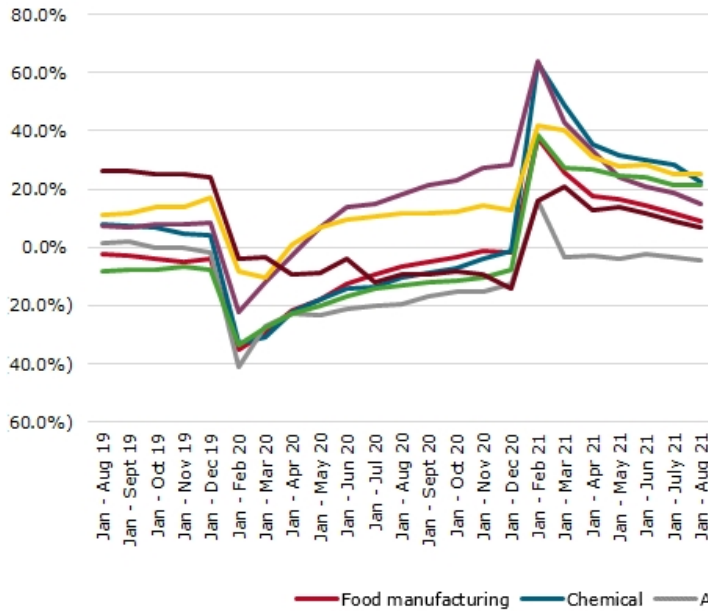
Value-added Industrial Output YoY Growth



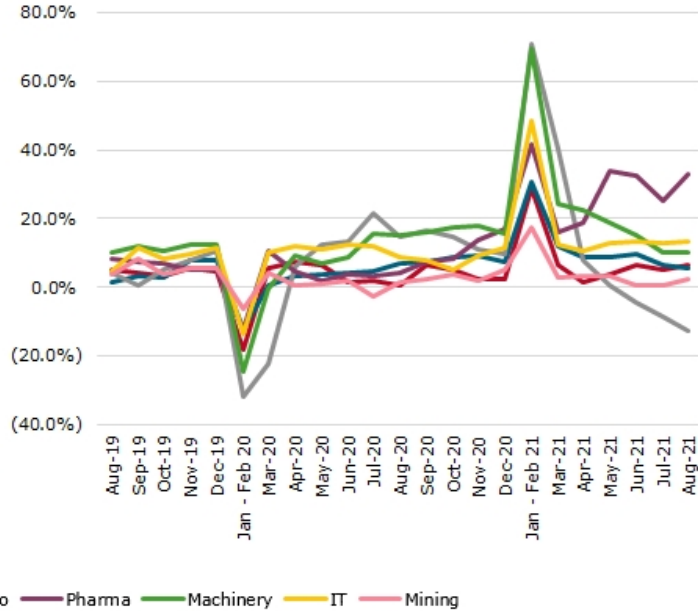
Source: China National Bureau of Statistics; Wells Fargo Securities, LLC

Source: China National Bureau of Statistics; Wells Fargo Securities, LLC

Fixed Asset Investment YoY Growth (by Industry)



Value-added Industrial Output YoY Growth (by Industry)



Source: China National Bureau of Statistics; Wells Fargo Securities, LLC

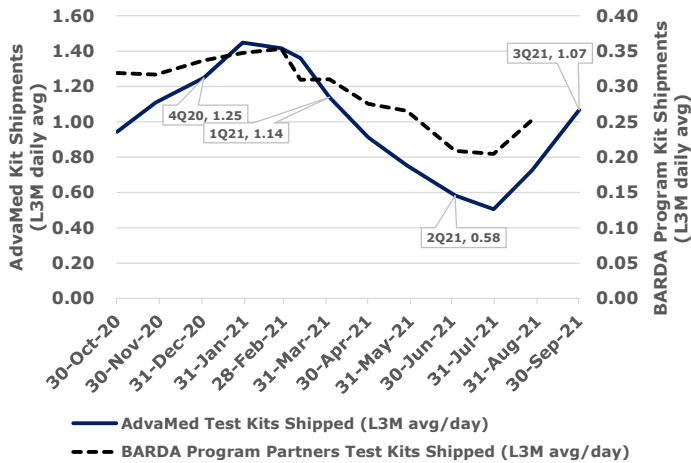
Clinical/Diagnostics End Market

Routine testing has largely returned to pre-COVID level (Exhibit 19-20) in Q3 with clinical volume still below pre-COVID level. As of August '21, while in-person patient volumes increased in almost all specialities, sales reps were still restricted from in-person doc detailing. Total in-person sales rep visits were up slightly by 2% m/m from July to ~63% of pre-COVID level. Despite the recent Delta variant impact, primary care in-person details held up well with a 4% increase m/m (+75% y/y) as companies have adapted to the new normal, and now sit at ~62% of pre-COVID level. However, oncology in-person details were down 3% m/m (+97% y/y) and sit roughly at ~38% of pre-COVID level (Exhibit 21 and 22).

COVID Test Kit shipments through the end of September imply 3Q21 ~2x 2Q21; US Antigen market becoming more competitive.

US test shipment data saw a slowdown in September vs. August, with supply now more aligned with demand following the start of the quarter where the number of PCR tests shipped by vendors was greater than used by labs. Overall 3Q21 average daily test kit shipments were at 1.07M/day vs. 2Q21 at 0.58 and 1Q21 at 1.14 (Exhibit 13). Rapid Antigen gained share over PCR in 3Q with the late summer / early fall COVID surge, but has given most of that back. President Biden in mid October announced +\$1B for rapid antigen testing in the US, incremental to \$2B announced in September. The FDA has been approving, and government funding, more rapid antigen test makers to increase capacity. Europe's higher antigen share (Exhibit 17) is from large govt population screening programs and a more competitive market with ~100x the number of rapid antigen COVID approvals in Europe vs. the US.

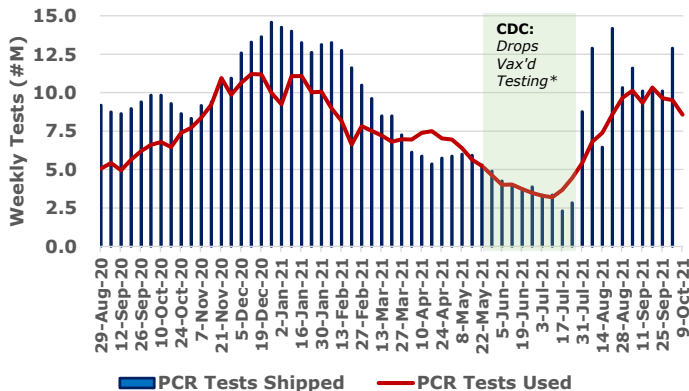
Exhibit 13: 3Q21 Avg Daily Test Shipment Volumes nearly on par with 1Q21



Source: Wells Fargo Securities, LLC estimates, Advamed, BARDA
 Note: US Only, L3M shipments avg/day, AdvaMed grossed to mkt w/ capture rate

Exhibit 14: US COVID PCR Test Volumes shipped (supply) outpaced those used (demand) in 3Q21

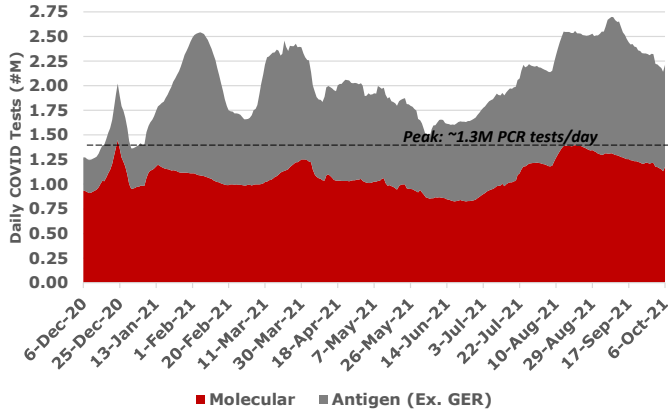
U.S. Weekly PCR COVID Test Volumes: Tests Shipped vs. Tests Used



Source: Wells Fargo Securities, LLC estimates, government data, industry data
 Note: PCR Tests Shipped/Ran based on data from Advamed/states, adj for capture
 Note: PCR Tests Shipped = PCR Extraction Reagents + Commercial Tests (kits)
 Note: * CDC 7/27 reverses 5/13 guidance change to not test asymptomatic vax'd people

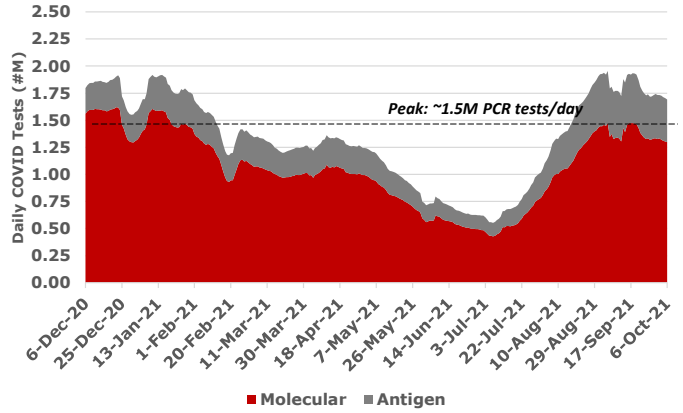
Exhibit 15 - 16: US and EU COVID Testing Volumes both touched peak in 3Q21

EU-5 Daily (L7D Avg) COVID Tests by Modality: PCR & Antigen



Source: Wells Fargo Securities, LLC estimates, govt. data
 Note: Germany does not disclose antigen volumes, but included in Molecular total shown
 Note: Final week in chart may be underrepresenting total figures due to reporting lag

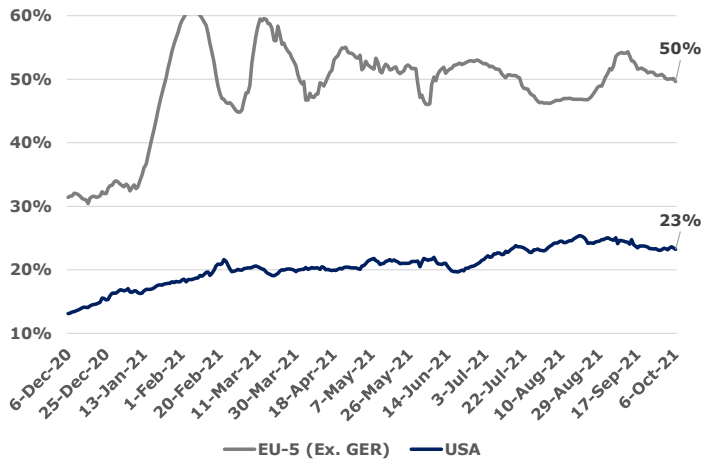
USA Daily (L7D Avg) COVID Tests by Modality: PCR & Antigen



Source: Wells Fargo Securities, LLC estimates, govt. data
 Note: Not all states disclose antigen, USA Total grossed up based on state capture %
 Note: Final week in chart may be underrepresenting total figures due to reporting lag
 Note: Data not included prior to Nov-20 due to lack of disclosures on antigen/PCR split

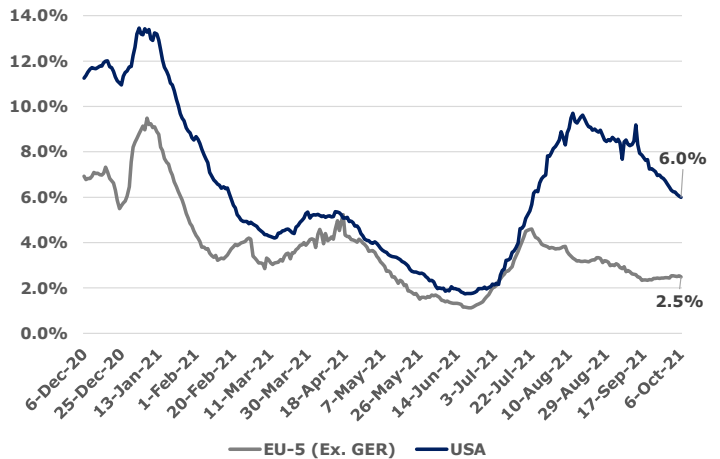
Exhibit 17 - 18: Antigen Testing ~50% of EU COVID Testing Market vs. ~25% in US; US Positivity Rates finally falling to acceptable levels - could enable more pooling

Antigen Share of Total COVID Tests (L7D Avg): EU-5 (Ex. GER) vs. USA



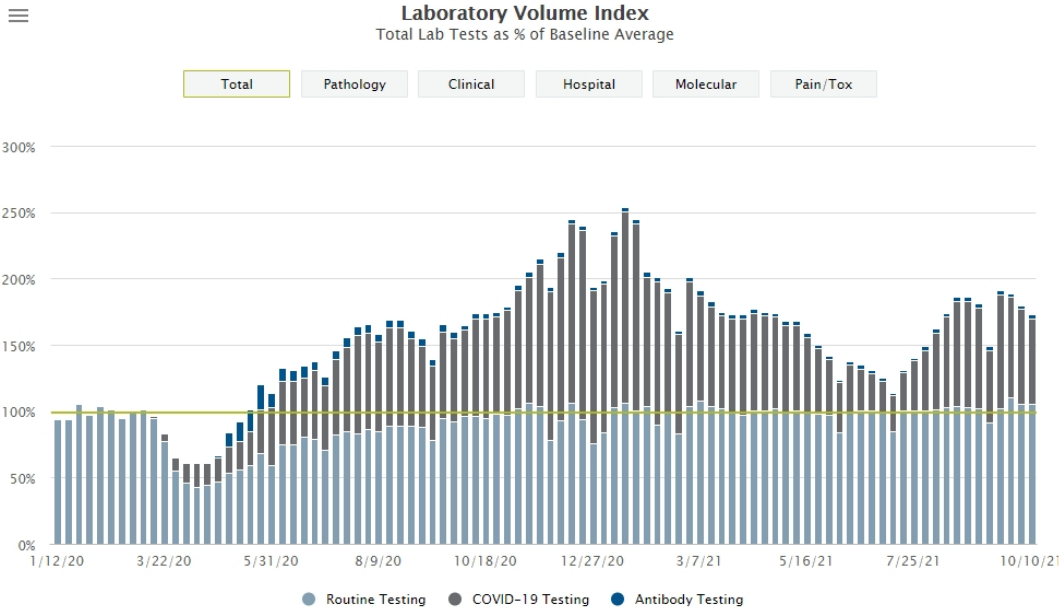
Source: Wells Fargo Securities, LLC estimates, govt. data
 Note: EU-5 (Ex. GER) like-for-like; excludes Germany due to lack of antigen data
 Note: Antigen Share (%) = Antigen Volumes / (Antigen + PCR Volumes)
 Note: US Data not included prior to Nov-20 due to lack of disclosures on antigen/PCR split

Positivity Rate of Total COVID Tests (L7D Avg): EU-5 (Ex. GER) vs. USA

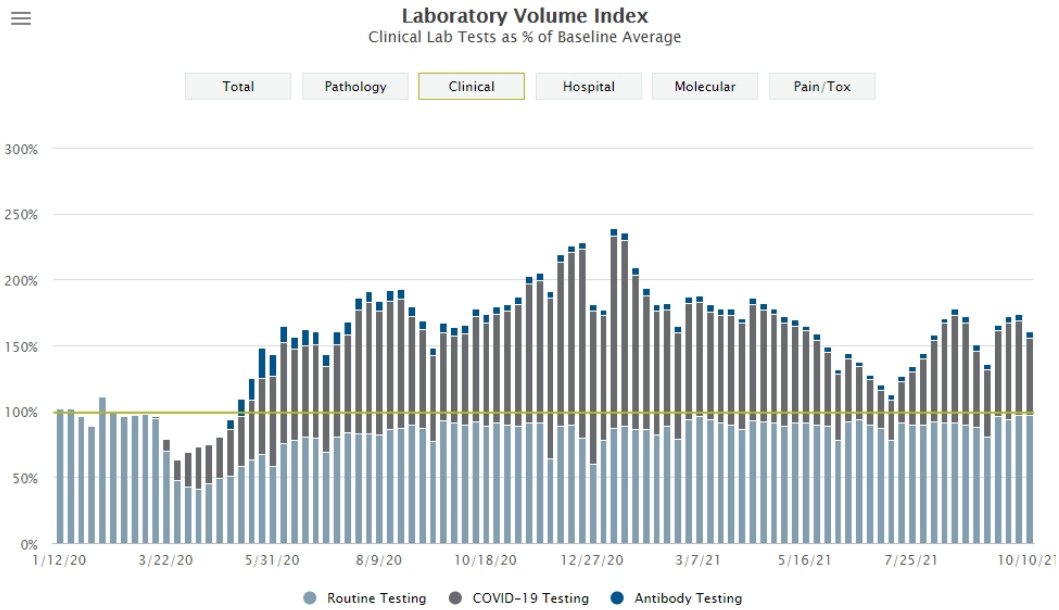


Source: Wells Fargo Securities, LLC estimates, govt. data
 Note: EU-5 (Ex. GER) like-for-like; excludes Germany due to lack of antigen data
 Note: Positivity Rate (%) = L7D New Cases / (L7D Antigen + PCR Volumes)
 Note: US Data not included prior to Nov-20 due to lack of disclosures on antigen/PCR split

Exhibit 19 - 20: Total laboratory testing volume has largely returned to normal, while clinical volume was still below pre-COVID level



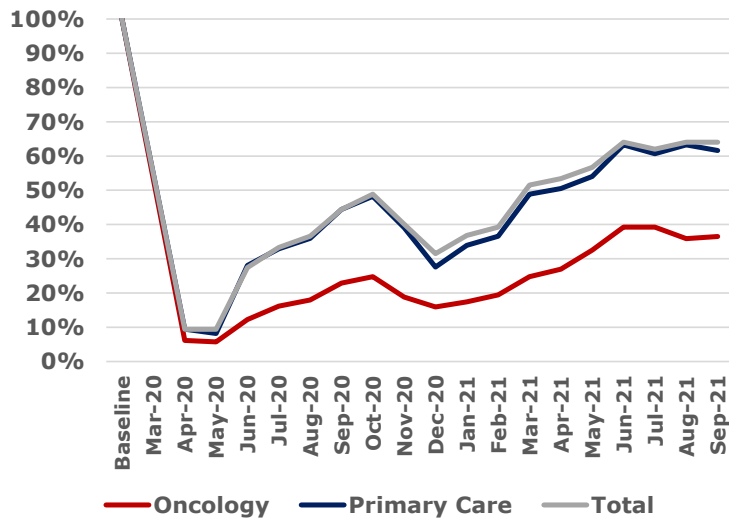
Source: XIFIN



Source: XIFIN

Exhibit 21: Doc detailing access pauses reopening progress with Delta flare-up

In-Person Details as % of Baseline: Oncology vs. PCP vs. Total



Source: Wells Fargo Securities, LLC, IQVIA

Note: Monthly In-person detailing volume as % of fixed baseline period volumes

Note: Total = Volume weighted median of all doctor office types

Note: Baseline period =monthly average of Jan and Feb 2020 detail volumes by doctor office type

Exhibit 22: Access Is still better than 2Q21 avg, not showing significant Delta pullback

Doc Detailing: In-Person Recovery Index

	<u>Oncology</u>	<u>Primary Care</u>	<u>Total</u>
Jan-Feb '20	100	100	100
1Q20	84	85	85
2Q20	8	15	15
3Q20	20	39	39
4Q20	20	38	40
1Q21	21	40	43
2Q21	33	56	58
3Q21	37	62	63

Source: Wells Fargo Securities, LLC, IQVIA

Note: Index represents the quarter avg of monthly detail volume as % of baseline period volumes

Note: Total = Volume weighted median of all doctor office types

Note: Baseline period =monthly average of Jan and Feb 2020 detail volumes by doctor office type

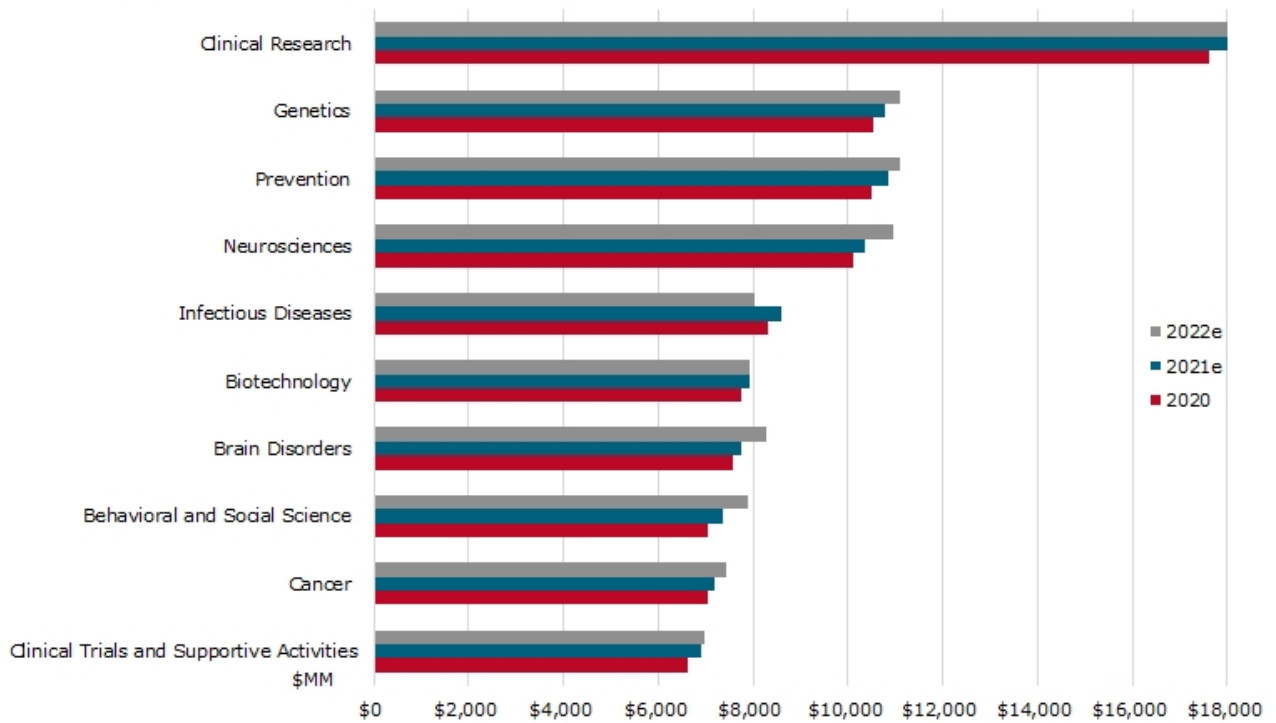
Academic/Government End Market

Longtime director of the National Institutes of Health (NIH), Francis Collins, announced his retirement from the agency on Oct 5th. Dr. Collins is the longest serving presidentially appointed NIH director, having served three U.S. presidents over more than 12 years, and during his tenure, NIH's budget grew by 38%.

The proposed FY22 NIH budget is still pending, but we expect the increase in budget will spur wide investment, especially in the research areas related to genetics, neurosciences, infectious diseases, biotechnology, brain disorders, cancers etc. (Exhibit 23)

Exhibit 23: ~35% NIH's funding go to research / disease areas related to clinical research, genetics, neurosciences, oncology etc.

NIH Fundings: Top 10 Research / Disease Areas (\$M)



Note: Funding levels for various research, condition, and disease categories are based on grants, contracts, and other funding mechanisms used across the National Institutes of Health (NIH)

Source: NIH RePORT

Labor Shortages and Wage Inflation impact will vary by End Market

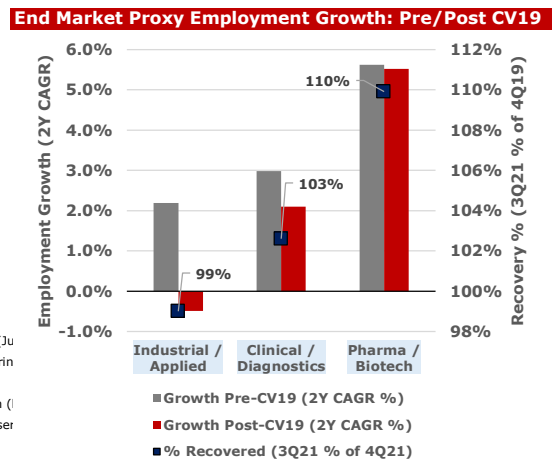
Biotech R&D hiring at an accelerating pace, well above other end markets and broader industry. Many companies in our space have highlighted concerns over the labor market, specifically over talent retention and subsequent wage inflation. We believe labor shortages will be less material for specific sub-sectors within our coverage vs. broader, less specialized, areas each end markets broader industry such as healthcare (i.e. nurses) and industrials (i.e. manufacturing labor). Analysis of U.S. Census / BLS data suggests growth in employment for most of our sub-sectors remains strong through the end of 3Q21 with total headcounts above pre-COVID levels (Exhibit 24). The major bullish standout we see is in Biotech R&D (i.e. Biopharma research) where employment levels are nearly ~20% above 4Q19 pre-COVID levels (Exhibit 30), while the most bearish area was Industrial / Applied Testing labs which are just below pre-COVID levels (Exhibit 25) and tracking well below the recovery in the broader industry. Wage inflation has accelerated in 2021 for most of our end markets but most seem to be in-line with broader inflation although some are accelerating. Clinical / Dx and Industrial / Applied proxy sectors are up MSD% while Biopharma manufacturing is seeing the most significant wage inflation, up HSD% vs. 4Q19 (Exhibits 33).

Exhibit 24: Life Science Tools, Dx and Pharma Services End Market Employment Levels mixed vs. pre-COVID levels

	Employment by End Market Avg Employees by Q ('000)					2Y CAGR Pre vs. Post CV19			Recovery 3Q21 % of 4Q19
	4Q17	4Q18	4Q19	4Q20	3Q21	4Q19	3Q21	Delta	
Industrial / Applied	170	174	178	172	176	2.2%	-0.5%	-2.7%	99%
Clinical / Diagnostics	272	276	289	287	296	3.0%	2.1%	-0.9%	103%
Pharma / Biotech	476	503	531	556	584	5.6%	5.5%	-0.1%	110%
Biotech R&D	182	202	221	239	258	10.2%	9.1%	-1.1%	117%
Production - Small mol.	206	207	212	215	217	1.6%	1.7%	0.1%	102%
Production - Large mol.	89	95	99	102	110	5.2%	5.6%	0.4%	111%

Source: Wells Fargo Securities, LLC, US Census

Note: CV19 = COVID; Pharma / Biotech the total of all three sub-industries; Clinical / Diagnostics 3Q21 Avg (July, Aug, Sept) vs. Others 3Q21 Avg (Jul Industrial / Applied = (NAICS lvi 4) Testing laboratories [parent hierarchy = (2) Professional and technical services / (3) Architectural and engineerin Clinical / Dx = (lvi 5) Medical and diagnostic laboratories [parent hierarchy = (3) Health care / (4) Ambulatory health care services] Pharma / Biotech represented by three sub-industries to represent research (Biotech R&D), small molecule production and large molecule production (Biotech R&D = (lvi 5) Research and development in biotechnology, except nanobiotechnology ; [parent hierarchy = (2) Professional and technical ser (3) Scientific research and development services / (4) Research and development in the physical, engineering, and life sciences Production - Small molecule = (lvi 4) Pharmaceutical preparations [parent hierarchy = (1) Nondurable Goods / (2) Chemicals / (3) Pharmaceuticals an Production - Large molecule = (lvi 4) Miscellaneous medicinal and biological products [parent hierarchy = (1) Nondurable Goods / (2) Chemicals / (3) Pharmaceuticals and medicines]

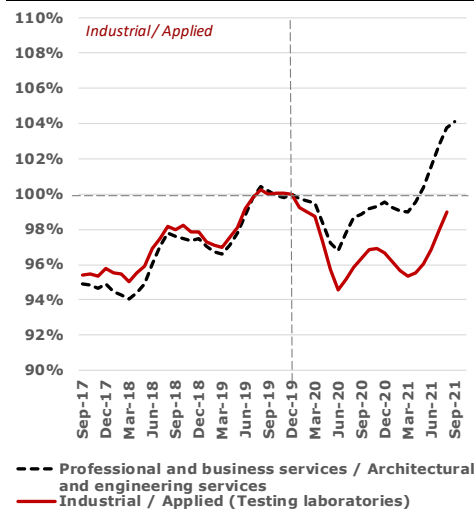


Industrial / Applied End Market

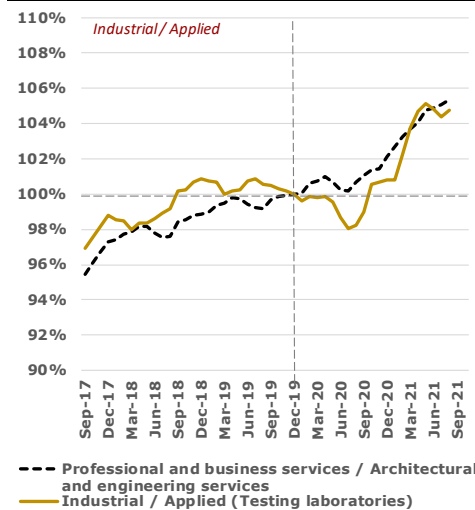
(-) Employment Growth (99% pre-COVID); well below broader industry // (=) Wage Inflation (105% pre-COVID); in-line with industry

Exhibit 25 - 26: Industrial / Applied Employment levels still yet to recover but wages have

Employment Levels (L3M Avg) - Pre vs. Post COVID (Base = 4Q19)
Industrial / Applied End Market vs. Broad Parent Industry



Hourly Wage Levels (L3M Avg) - Pre vs. Post COVID (Base = 4Q19)
Industrial / Applied End Market vs. Broad Parent Industry



Source: Wells Fargo Securities, LLC, US Census

Note: Broad Parent Industry based on NAICS hierarchy parent node; End Market proxy based on relevant child level node under parent industry Industrial/Applied= (NAICS lvi 4) Testing laboratories [parent hierarchy= (2) Professional and technical services / (3) Architectural and engineering services]

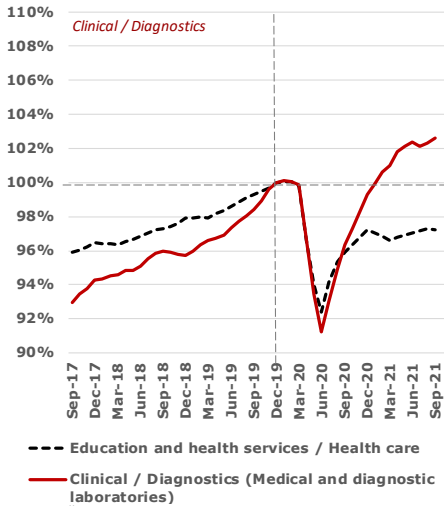
Clinical / Diagnostics End Market

(+) Employment Growth (103% pre-COVID); well above broader industry

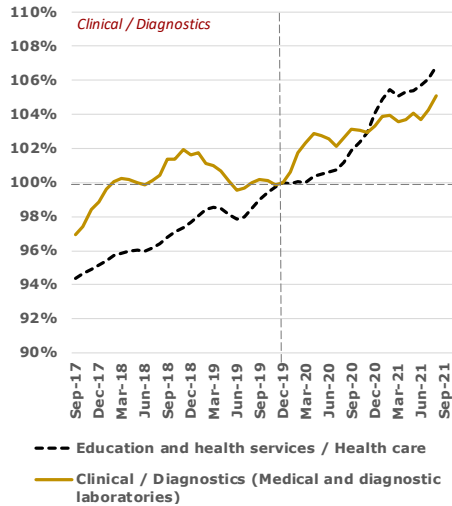
(=) Wage Inflation (105% pre-COVID); below broader industry but accelerating

Exhibit 27 - 28: Clinical / Diagnostics Employment has rebounded much faster than healthcare, still just above pre-COVID; wage inflation a rising concern

Employment Levels (L3M Avg) - Pre vs. Post COVID (Base = 4Q19)
Clinical / Diagnostics End Market vs. Broad Parent Industry



Hourly Wage Levels (L3M Avg) - Pre vs. Post COVID (Base = 4Q19)
Clinical / Diagnostics End Market vs. Broad Parent Industry



Source: Wells Fargo Securities, LLC, US Census
Note: Broad Parent Industry based on NAICS hierarchy parent node; End Market proxy based on relevant child level node under parent industry
Clinical / Dx = (lvl 5) Medical and diagnostic laboratories [parent hierarchy = (3) Health care / (4) Ambulatory health care services]

Pharma / Biotech End Market - Biotech R&D vs. Drug Manufacturing

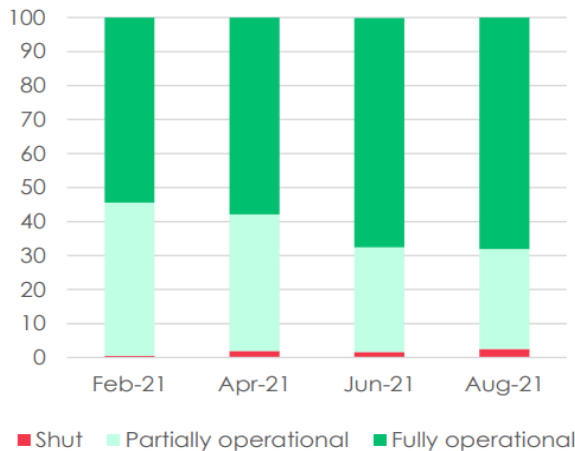
Biotech R&D

(+ +) Employment Growth (117% pre-COVID); well above broader industry and other end markets

(=) Wage Inflation (102% pre-COVID); in-line with broader industry

Exhibit 29: Global Research labs still have reopening tailwinds, but Academic dragging down while Biopharma likely higher

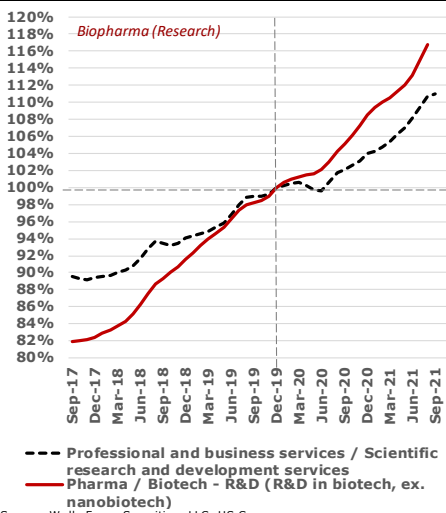
Global research lab status²



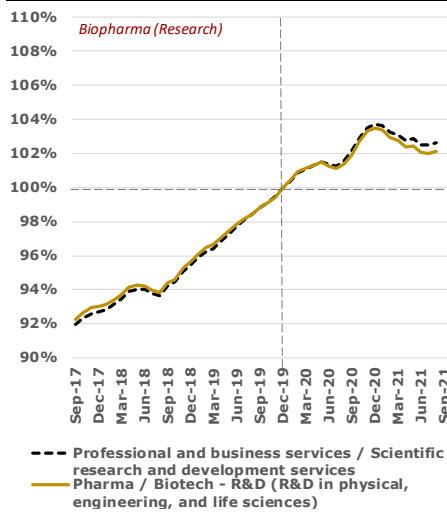
Source: Abcam customer surveys, company presentations

Exhibit 30 - 31: Biopharma Research & Development showing the strongest employment growth, wage inflation modest

Employment Levels (L3M Avg) - Pre vs. Post COVID (Base = 4Q19)
Pharma / Biotech (Research) End Market vs. Broad Parent Industry



Hourly Wage Levels (L3M Avg) - Pre vs. Post COVID (Base = 4Q19)
Pharma / Biotech (Research) End Market vs. Broad Parent Industry



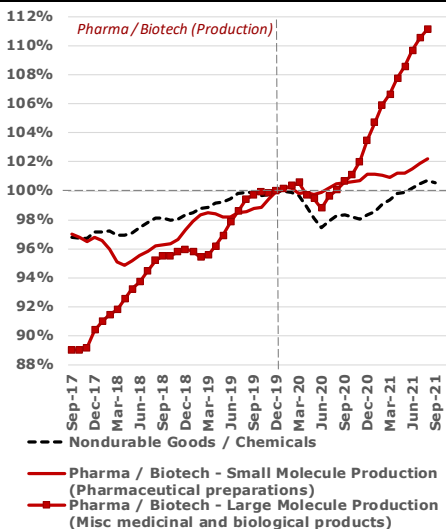
Source: Wells Fargo Securities, LLC, US Census
 Note: Broad Parent Industry based on NAICS hierarchy parent node; End Market proxy based on relevant child level node under parent industry
 Pharma / Biotech represented by three sub-industries to represent research (Biotech R&D), small molecule production and large molecule production (bioprocess);
 Biotech R&D = (lvl 5) Research and development in biotechnology, except nanobiotechnology; [parent hierarchy = (2) Professional and technical services / (3) Scientific research and development services / (4) Research and development in the physical, engineering, and life sciences
 Pharma / Biotech (Research) sub-sector shown for Biotech only for employment levels; data not available for wages so use +1 node higher

Drug Manufacturing

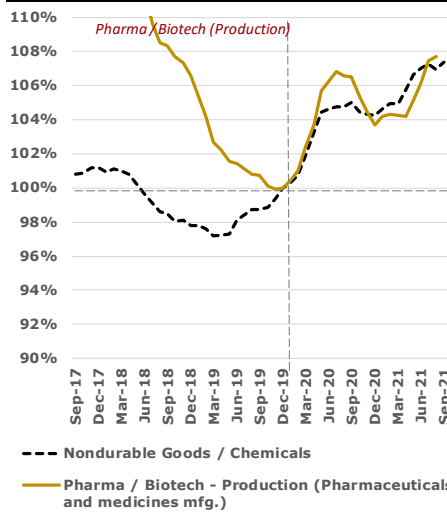
- (+) Large Molecule Headcount growth (111% pre-COVID); well above broader industry
- (=) Small Molecule Headcount growth (102% pre-COVID), in-line with broader industry
- (- -) Wage Inflation (108% pre-COVID); in-line broader market but accelerating, well above other end markets

Exhibit 32 - 33: Pharma / Biotech Production employment growth shows Large Molecule strength, but industry wage pressure greater than most

Employment Levels (L3M Avg) - Pre vs. Post COVID (Base = 4Q19)
Pharma / Biotech (Production) End Market vs. Broad Parent Industry



Hourly Wage Levels (L3M Avg) - Pre vs. Post COVID (Base = 4Q19)
Pharma / Biotech (Production) End Market vs. Broad Parent Industry



Source: Wells Fargo Securities, LLC, US Census
 Note: Broad Parent Industry based on NAICS hierarchy parent node; End Market proxy based on relevant child level node under parent industry
 Pharma / Biotech represented by three sub-industries to represent research (Biotech R&D), small molecule production and large molecule production (bioprocess);
 Small molecule= (lvl 4) Pharmaceutical preparations [parent hierarchy = (1) Nondurable Goods / (2) Chemicals / (3) Pharmaceuticals and medicines];
 Large mol= (lvl 4) Miscellaneous medicinal and biological products [parent hierarchy= (1) Nondurable Goods / (2) Chemicals / (3) Pharmaceuticals and medicines];
 Pharma/Biotech (Production) large and small molecule production sub-sectors for employment levels; data not available for wages so use +1 node

2H21 winners could be those hurdling "MSD%+" stacked growth

Tools, Diagnostics and Pharma Services - 3Q21 KPI will be hurdling MSD%+ growth for 2H21+

KPIs are facing tough comps, but winners will be those who can keep stacked comps steady. Approaching tough comps, a focus for 3Q results will be on stacked growth rates and the ability to maintain or even improve those levels in 2H21 vs. 1H21. Exhibit 34 shows year to date results as well as our forecasts.

Exhibit 34: Tools/Dx Group YTD21 Results and Outlook for steady MSD%+ stacked growth

CY	Yr/Yr Core Organic Growth					Core Organic Growth vs. 2019					Stacked 2-Yr Core Organic Growth				
	1Q21A	2Q21A	3Q21E	4Q21E	2021E	1Q21A	2Q21A	3Q21E	4Q21E	2021E	1Q21A	2Q21A	3Q21E	4Q21E	2021E
A	18%	21%	10%	9%	14%	15%	15%	14%	18%	16%	8%	8%	7%	9%	8%
AVTR	9%	18%	10%	5%	10%	13%	10%	12%	11%	11%	7%	5%	6%	5%	6%
BIO	11%	33%	14%	15%	18%	12%	11%	11%	13%	12%	6%	8%	6%	7%	6%
BRKR	22%	28%	12%	8%	17%	13%	10%	5%	5%	8%	7%	7%	3%	3%	5%
DHR	12%	17%	8%	6%	10%	14%	13%	12%	13%	13%	7%	7%	6%	6%	6%
HOLX	7%	64%	0%	0%	13%	8%	6%	-8%	6%	3%	4%	14%	-4%	3%	2%
ILMN	21%	68%	32%	14%	31%	23%	27%	16%	14%	19%	11%	22%	10%	7%	11%
MTD	16%	24%	16%	4%	14%	12%	20%	21%	10%	15%	6%	10%	10%	5%	8%
PKI	10%	28%	11%	11%	15%	7%	10%	4%	8%	7%	4%	7%	3%	4%	4%
QGEN	9%	49%	23%	23%	25%	5%	16%	12%	10%	11%	3%	13%	7%	6%	7%
TECH	19%	44%	19%	15%	23%	26%	26%	27%	34%	28%	12%	16%	13%	16%	14%
TMO	10%	27%	7%	9%	13%	10%	13%	10%	12%	11%	5%	8%	5%	6%	6%
WAT	22%	25%	9%	9%	15%	12%	9%	10%	12%	11%	7%	6%	5%	6%	6%
Median	12.0%	27.9%	11.0%	8.7%	14.7%	12.2%	13.0%	12.3%	12.3%	11.5%	6.5%	8.0%	6.0%	6.1%	6.4%

Source: Wells Fargo Securities, LLC estimates

Note: All quarters shown on CY equivalent basis; Core = excluding COVID Testing and COVID Vax/Rx revenues; Grey = actual, White = estimate

Note: AVTR, DHR, HOLX, TMO, WAT adjusted for selling days; QGEN adjusted to include non-COVID testing but COVID related products revenue in core

Note: ILMN legacy only shown (not incl GRAIL); TMO shown on legacy core basis, before COVID vax/rx was reclassified as core

Exhibit 35: Pharma Services Group Results similarly strive for MSD%+ steady growth

CY	Yr/Yr Core Organic Growth					Core Organic Growth vs. 2019					Stacked 2-Yr Core Organic Growth				
	1Q21A	2Q21A	3Q21E	4Q21E	2021E	1Q21A	2Q21A	3Q21E	4Q21E	2021E	1Q21A	2Q21A	3Q21E	4Q21E	2021E
CRL	12%	16%	13%	10%	13%	21%	18%	22%	21%	20%	10%	9%	11%	10%	10%
DGX	1%	6%	15%	14%	9%	-5%	-34%	4%	6%	-7%	-3%	-16%	3%	3%	-3%
ICLR	18%	40%	19%	15%	22%	29%	35%	21%	24%	27%	13%	18%	10%	11%	13%
IQV	9%	22%	18%	13%	16%	12%	12%	11%	13%	12%	6%	7%	6%	7%	6%
LH	12%	36%	10%	3%	14%	11%	7%	8%	7%	8%	5%	7%	4%	3%	4%
Median	11.6%	22.1%	15.3%	13.4%	14.1%	11.9%	12.4%	10.6%	13.2%	12.0%	5.9%	7.4%	5.9%	6.6%	6.3%

Source: Wells Fargo Securities, LLC estimates

Note: All quarters shown on CY equivalent basis; Grey = actual, White = estimate; CRL management "core" excl 2020 COVID shortfall; DGX shown ex-COVID;

ICLR no adjustment organic reported = core; IQV ex COVID; DGX ex COVID

Emerging Growth Players Unlikely to impress

Emerging growth diagnostics names are facing high expectations and pending data. As with other quarters, traditional financial results are less important than Industry KPIs; with penetration, reimbursement environment and data timelines in focus. Our 2H21 outlook implies a deceleration in stacked growth rates from MDD% to MDD-LDD% from 1H to 2H21.

Exhibit 36: Emerging Growth Diagnostics Group facing decelerating growth, messaging the slowdown key

CY	Yr/Yr Core Organic Growth					Core Organic Growth vs. 2019					Stacked 2-Yr Core Organic Growth				
	1Q21A	2Q21A	3Q21E	4Q21E	2021E	1Q21A	2Q21A	3Q21E	4Q21E	2021E	1Q21A	2Q21A	3Q21E	4Q21E	2021E
EXAS	6%	71%	37%	24%	31%	37%	28%	27%	32%	30%	17%	23%	15%	15%	15%
GH	6%	42%	33%	39%	30%	121%	73%	54%	57%	70%	57%	32%	24%	26%	30%
NTRA	36%	71%	60%	53%	55%	87%	111%	123%	119%	110%	37%	47%	50%	48%	45%
NVTA	44%	128%	67%	30%	58%	129%	96%	102%	77%	97%	51%	57%	44%	33%	41%
Median	21%	71%	49%	35%	43%	104%	84%	78%	67%	83%	44%	39%	34%	29%	36%

Source: Wells Fargo Securities, LLC estimates

Note: All quarters shown on CY equivalent basis; EXAS excl COVID revenues; GH Total Precision Oncology Rev growth; NTRA Total Genetic Testing product revenue growth

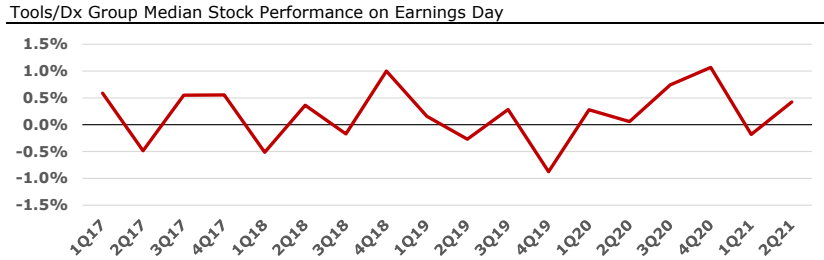
NVTA Organic Test Revenue Growth; Grey = actual, White = estimate

Historical Stock Reactions to Earnings Surprise have been erratic, don't expect much upside this time around

Historically earnings day stock performance erratic at best, but this quarter is an uphill battle

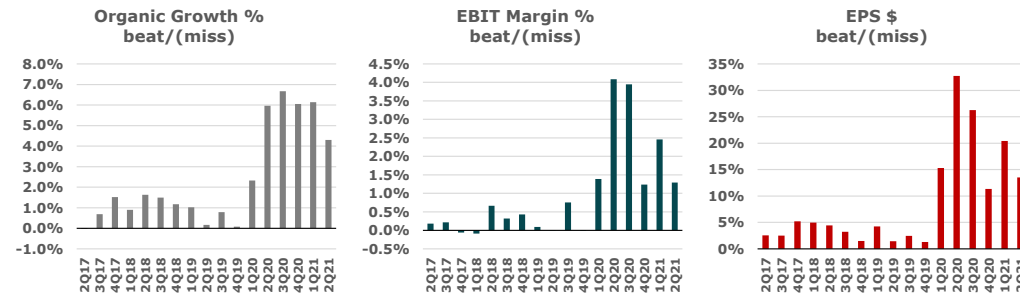
Over the past few quarters, with all the noise in Core vs. COVID trends, the historical trend where a beat/raise earnings day would drive stock outperformance has broken down, with limited upside (and some cases downside) from a beat/raise as shown in Exhibits 37-39.

Exhibit 37: Tools/Dx Group Stock Performance on earnings day has not followed beats



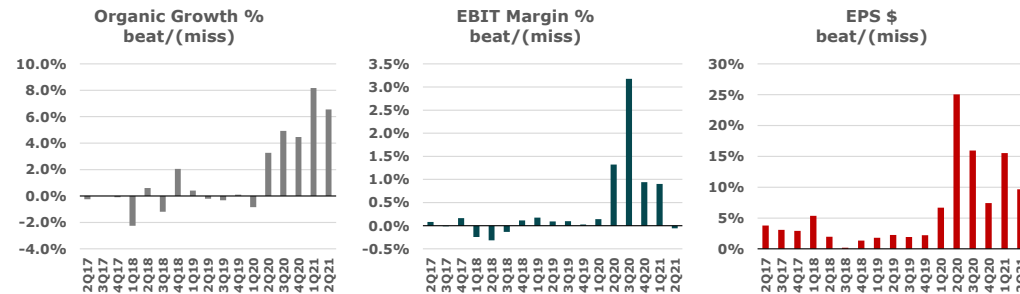
Source: Wells Fargo Securities, LLC, Factset
Median includes A, AVTR, BIO, BRKR, DHR, HOLX, ILMN, MTD, PKI, QGEN, TECH, TMO, WAT

Exhibit 38: Tools' Group earnings beats remained elevated through last quarter



Source: Wells Fargo Securities, LLC, Factset
Note: beat/(miss) based on median of Tools/Dx group upside (downside) to consensus KPI estimates; EPS (\$act/\$exp-1), Margin & Growth (%act - %exp)
Median includes A, AVTR, BIO, BRKR, DHR, HOLX, ILMN, MTD, PKI, QGEN, TECH, TMO, WAT

Exhibit 39: Pharma Services Group also saw outsized beats for most KPIs through 2Q21



Source: Wells Fargo Securities, LLC, Factset
Note: beat/(miss) based on median of PharmaSrv group upside (downside) to consensus KPI estimates; EPS (\$act/\$exp-1), Margin & Growth (%act - %exp)
Median includes CRL, DGX, ICLR, IQV and LH

COVID Beats not impressing the market anymore, at least for Testing as companies try to fold Vax/Rx into Core

Recent pre-announcements with strong COVID beats have seen limited appreciation by the market. So far DGX and QDEL have pre-announced with upside to consensus expectations due to stronger COVID testing demand. Both stocks closed the first trading day post-update effectively flat.

Exhibit 40: Pre-announced 3Q21 Upside from COVID testing shrugged off by the market

Company	Pre-Announce Stock Reaction				COVID Guidance Upside (FY21)			
	Date	Close	Prior	% ch	Metric	New Guide	Consensus	% Upside
QDEL	8-Oct-21	\$138.04	\$136.21	1.3%	Revs	\$1,283	\$961.00	33.5%
DGX	9-Sep-21	157.35	158.00	-0.4%	Adj EPS	12.00	11.41	5.2%

Source: Wells Fargo Securities, LLC, Factset consensus estimates
 Note: Consensus as of T-1D of Guidance Update; New Guidance shown at mid-point of range
 QDEL FY21 "New Guide" = prior FY21e consensus revenues + revenue upside to prior 3Q21e expectations

Ticker	Rating	Target	Price
A	Overweight	\$180.00	\$152.59
AVTR	Overweight	44.00	37.54
BIO	Overweight	930.00	720.11
TECH	Equal Weight	490.00	497.85
BRKR	Equal Weight	85.00	76.31
CRL	Overweight	470.00	405.84
DHR	Overweight	320.00	300.43
HOLX	Overweight	90.00	70.26
ICLR	Overweight	280.00	275.07
ILMN	Underweight	350.00	408.10
IQV	Overweight	290.00	246.82
LH	Overweight	325.00	275.71
MTD	Equal Weight	1,500.00	1,399.31
PKI	Overweight	190.00	169.68
QGEN	Equal Weight	57.00	51.81
DGX	Equal Weight	140.00	142.41
STVN	Overweight	25.00	24.68
TMO	Equal Weight	560.00	577.35
WAT	Underweight	\$330.00	\$344.94
EXAS	Equal Weight	\$120.00	\$97.75
GH	Overweight	160.00	104.24
NTRA	Overweight	135.00	113.37
NVTA	Equal Weight	\$35.00	\$27.73

Source: Wells Fargo Securities, LLC estimates, Factset

Note: prices as of cob 10.14.21

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EXHIBIT 50

Growth Life Science Tools & Diagnostics

Questions & Themes for J.P. Morgan Healthcare Conference

Heading into our in-person 2023 healthcare conference next week, we have aggregated key themes, questions, and pre-announcement / guidance expectations for the 17 companies in our coverage universe that will be attending. For additional thoughts on the group, please see our recently published [Outlook Slide Deck](#) and [Outlook Report](#).

Life Science Tools & Diagnostics

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2023 Outlook

Growth Life Science Tools & Diagnostics experienced a rough 2022 with macro headwinds and idiosyncratic execution challenges pressuring both growth trends and valuation levels, with many companies seeing deep multiple compressions and falling below pre-pandemic levels. Looking into 2023, while macro headwinds are expected to linger, attractive valuation and select catalyst / event paths point to pockets of opportunities for those with patience. Our top picks for 2023 are NTRA (OW, Analyst Focus List) and RGEN (OW), and our top watch list for 2023 includes CTLT (OW), TXG (OW), and ILMN (N).

Growth Trend

Growth tools: Growth Tools companies saw a growth slowdown in 2022 as macro headwinds (FX, supply chain, biotech funding) led to lengthening sales cycles and customer project delays. Some companies with new product cycles (e.g., ILMN, PACB, NSTG) saw further headwinds from near-term air pockets ahead of new product launches.

Liquid biopsy: Lingering COVID headwinds continue to cast residual impact on clinical testing volumes but should set up 2023 well on easy comps.

Bioprocessing: COVID roll-off led to a sharp growth deceleration for bioprocessing companies. Despite destocking and ordering lead time normalization headwinds, bioprocessing equipment vendors are still sustaining significantly higher growth vs. CDMOs.

Valuation Trend

Following the pandemic rally, valuations for Growth Life Science names have fallen below pre-pandemic levels. In particular, LBx companies saw an average of 6.7x sales multiple compression. Genetic Analysis companies also saw an average of 1.6x sales multiple compression from

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pre-pandemic levels. Within the large cap group, ILMN's -12x EV/EBITDA (excluding Grail) multiple compression (from 34x to 22x) and CTLT's -4x EV/EBITDA multiple compression (from 13.5x to 9.5x) are also particularly noteworthy.

Sequencing

Illumina (N): Grail divestiture to lift some residual valuation overhang (15% upside), although implementation would take 9-18 months. The question is how much funding ILMN needs to provide Grail (burning ~\$1.6B cash through 2025) and how it plans to recoup the investment. Core ILMN long-term positioning is well supported by price elasticity and extended IP protection, but macro headwinds (popseq recruitment delays) and NovaSeq 6000 ramp down may cause near-term risk.

PacBio (OW): We believe PACB remains highly competitive on a recurring cost basis, with the only hurdle being the up-front capital cost given lower-capex or no-capex alternatives. But customers should be willing to pay up for PACB's higher-quality data and epigenetics capabilities.

Spacial Biology

TAM calculation: We conservatively estimate an addressable customer base of 2,000+ labs for discovery research, 1,000+ labs for translational research, and 2,000+ labs for clinical use, leaving ample runway for spatial players despite growing competition.

Competitive landscape: We introduce a framework that ranks eight key performance aspects of a spatial imager in terms of importance to users and differentiation among vendors. The top three aspects are plexity, publications, and sensitivity. We don't think spatial imagers cannibalize spatial profilers. Although near term customer budget may be siphoned from profilers to imagers, profilers will remain important for initial discovery, although they'll likely compete with single-cell RNA-seq.

Liquid Biopsy

MRD TAM calculation: We conservatively expect the MRD market to reach 2.7M tests and \$2B revenue (from just four indications) by 2030, assuming \$750 ASP despite significantly higher CMS rates, suggesting significant long-term upside, especially for NTRA given its leading market share.

Guardant Health (OW): While the binary focus on ECLIPSE readout has exacerbated the initial stock reaction and while competitive noise will likely linger, we believe SHIELD's commercial potential as a first-in-class blood-based screening test and its ability to unleash a vast TAM of unscreened population remains intact. Post-ECLIPSE sell-off has wiped out the majority of SHIELD value, leaving the asset as an upside. We believe solid execution on SHIELD's commercial rollout and regulatory / reimbursement / guideline pathways should drive significant upside over time.

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Bioprocessing Highlights

Destocking and order normalization: Unlike the last wave of destocking in 2017, which spread across all biopharma companies, the current wave of destocking is more limited in scope (mainly affecting COVID vaccine manufacturers and smaller ticket items that didn't face supply constraint). The ordering lead time normalization cycle started in 2Q22 and is expected to last three to four quarters (per 2017 experience), so the headwind is expected to wane in 2H23, which will lead to sentiment improvement.

CDMO capacity supply and demand: Excess capacity affects drug product more than drug substance. C> is seeing the greatest capacity shortage, with pipeline progression to drive >30% volume scale-up y/y, while biosimilars should sustain traditional mammalian capacity utilization. Reshoring of demand benefits US CDMOs.

Figure 1: J.P. Morgan Healthcare Conference Tracker

JP Morgan Healthcare Conference Tracker

Life Science Tools & Diagnostics

Company	2022 JPM		2021 JPM		2020 JPM		2019 JPM		2018 JPM	
	Pre-announced C4Q or revised C4Q guide	2022 Guide	Pre-announced C4Q or revised C4Q guide	2021 Guide	Pre-announced C4Q or revised C4Q guide	2020 Guide	Pre-announced C4Q or revised C4Q guide	2019 Guide	Pre-announced C4Q or revised C4Q guide	2018 Guide
10x Genomics (TXG)	No	No	No	No	No	No	-	-	-	-
Absci (ABSI)	No	No	-	-	-	-	-	-	-	-
Adaptive Biotechnologies (ADPT)	Yes	No	No	No	-	-	-	-	-	-
Akoya (AKYA)	No	No	-	-	-	-	-	-	-	-
Berkeley Lights (BLI)	Yes	Yes	No	No	-	-	-	-	-	-
Catalent (CTLT)	No	Yes	No	No	No	No	No	No	No	No
Guardant Health (GH)	No	No	No	No	No	No	-	-	-	-
Illumina, Inc. (ILMN)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Invitae (NVTI)	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No
Myriad Genetics Inc. (MYGN)	No	Yes	No	No	No	No	No	No	No	No
NanoString (NSTG)	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Natera (NTRA)	Yes	No	No	No	No	No	No	No	No	No
Pacific Biosciences (PACB)	Yes	No	Yes	No	-	-	-	-	-	-
Repligen (RGEN)	No	No	No	No	No	No	No	No	No	No
Seer (SEER)	No	No	No	No	-	-	-	-	-	-
Singular Genomics (OMIC)	No	No	-	-	-	-	-	-	-	-
Sophia Genetics (SOPH)	No	Yes	-	-	-	-	-	-	-	-

Source: Company reports

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Company Profiles

Growth Tools

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Akoya

Management recently indicated confidence in achieving +35% growth in 4Q. Focus is on incremental contribution from new products recently announced at the Analyst Day, as well as the competitive landscape.

End market

- Can you remind us of your current customer mix between biopharma vs. CRO vs. academia as you begin to tap into the genomics and discovery space?
- Have you seen the spatial labs being more impacted by macro headwinds than genomics labs or vice versa? What about the macro impact on clinical customers vs. discovery customers?
- With continued improvement in throughput, multiplexing capability, and new instrument launches, where are we in addressing the \$14B TAM? What needs to happen to support sustainable growth in the spatial market? What do you estimate your market share to be?
- What do you think is bottlenecking broader adoption of spatial imagers in biopharma or clinical other than throughput and costs?
- Who do you consider to be your main competitors in the space? How do you differentiate? Also, unlike many of your peers, and despite weakening macro environment, you have been consistently executing. What do you attribute to that to? What are your key competitive advantages?

Products

- You expect to launch PhenoCycler Fusion 2.0 in 1H23. Have you started taking pre-orders? If so, what does your order book look like? What customer types showed the most interest?
- What is your expectation for PhenoCycler Fusion 2.0 in terms of revenue ramp for 2023 and 2024? Do you expect it to be mostly from existing customers upgrading or new customers?
- How do you envision the transition to PhenoCycler Fusion 2.0 from existing customers?
- How should we think about profit margins for PhenoCycler Fusion 2.0? Is it in line with the original PhenoCycler Fusion? What about the list price?
- How should we think about Universal PhenoCode rollout and initial uptake? Have you started taking pre-orders? If so, what does your order book look like?
- Regarding Universal PhenoCode, what feedback have you heard from potential customers regarding your five panel approach?
- You expect to see 2-3x pull-through increase (vs. \$30-35K currently) from adoption of Cycler-Fusion and PhenoCode. How quickly can we see this to happen? What factors may slow the ramp?

Operating model

- As we look toward 2023, keeping in mind your long-term guidance and on the back of new product launches, what should we be thinking about in terms of growth?

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What are potential sources of upside and downside?

- How should we think about consumables revenue in 2023? What are the relative contributions from each type of consumables by category?
- What are the levers that you have pull to improve gross margin?

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Illumina

Management recently provided a preliminary 2023 outlook of +10% growth. Focus is on upside/downside to this outlook in light of macro headwinds, NovaSeq 6000 utilization trends in 4Q, an update on NovaSeq X order book, as well as management's latest plans for Grail divestiture.

General

- As we think about 2023, what are the main sources of upside and downside to your preliminary guidance in your opinion?
- What can you tell us about NovaSeqX order book in 4Q relative to your expectations?
- How should we interpret customer destocking in terms of macro headwinds vs. shifting in end market demand? When will we begin to see normalization of consumable orders?
- When do you expect those delayed clinical lab expansions to catch up? How significant will the impact of macro headwinds be next year compared to what we have already seen.
- What kind of discounts are you applying to revenue contribution from popseq programs that are currently underway? How much contributed recruitment delays are you assuming? How much upside or downside is there to your outlook?
- How quickly are new programs ramping in the pipeline, especially healthy system and biobank projects, and how soon we can see material revenue contribution?
- How to think about core ILMN margin in 2023? You have NovaSeq X initial launch dilution, lingering macro headwinds, but also the benefit of a 5% workforce reduction.

Products

- How is the order book of NovaSeq X? What is the customer split in terms of research vs. clinical? Does the mix continue to be skewed toward clinical?
- Your initial expectation for 300 NovaSeq shipments this year appears highly conservative. What would the potential upside look like?
- What's the maximum instrument manufacturing capacity of NovaSeq X that you hope to reach in 2H?
- How should we think about the consumable ramp of NovaSeq X? How quickly can we see the 3x pull through as you are expecting?
- What are the reasons to launch the 10B read flow cell first rather than the 25B read flow cell? How should we think about the ramp of 10B read flow cell vs. 25B read flow cell? What are the implications on pull-through into 2023, and how will that compare to the flow cell for '6000'?
- What are you assuming for residual NovaSeq 6000 instrument placement and consumable pull-through?
- How should we think about the value proposition of the Complete Long-Read in the long-read sequencing space, given the launch of Revio from PacBio?

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Grail

- The EC letter says Grail’s independence should be restored “swiftly.” How are you interpreting that wording in terms of a specific time frame?
- Regarding the Grail divestiture, which divestiture option looks the most promising?
- How much funding does Grail need as a stand-alone company, and what is the latest cash run rate for Grail?

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NanoString

The company recently issued 2023 guidance with 3Q earnings. Focus is on CosMx order book, GeoMx instrument and consumable trends in 4Q, long-term outlook on GeoMx demand, nCounter stability, and upside/downside to 2023 outlook.

Spatial

- The 4Q and FY23 guidance at the lower end implies no improvements in GeoMx pull through and flat instrument growth. What specific dynamics have influenced this guidance for GeoMx? Is that mainly elevated interest in CosMx for instruments and macro headwinds and lumpy orders on the pull-through side? Do you anticipate the order lumpiness to continue despite 4Q typically having seasonally higher consumables orders?
- On the 3Q call, you mentioned that about one-third of the installed base for GeoMx is under a year old. It takes about 12 months for new accounts to reach steady-state utilization. So would it be correct to assume that we should see normalization toward historical pull through in about two quarters (since installed and activated in 1H2022)? Your guidance implies no improvements for next year. Why?
- What are your long-term expectations for consumable pull-through for GeoMx? Should we anticipate it to return to historical norms? Specifically if you think about your existing GeoMx installed base that ordered CosMx vs. existing installed base that did not order CosMx, do you anticipate significant differences in consumable pull through between these two groups?
- Regarding demand for GeoMx, what are you seeing in terms of demand from translational vs discovery researches? Also, could you comment on the current mix of translational vs discovery researches for your current installed base of GeoMx?
- What are your expectations for CosMx instrument orders in 2023 given the strong performance in 2022?
- You previously mentioned that you do not expect CosMx orders to cannibalize GeoMx. However, given the strong traction in CosMx and relative weakness in GeoMx so far this year, have your views changed? How should we think about the complementary vs cannibalizing nature of the two systems?
- How should we think about CosMx pull through potential ramp up? Do you anticipate it to be similar to GeoMx's?
- On the 3Q call it was mentioned that about two-thirds of CosMx orders came from new to NSTG customers. One-third of these new customer orders came from customers who bought a bundle of CosMX and GeoMx. How has this mix changed since the announcement of CosMx, and are you seeing continued demand for bundles?
- On the 3Q call you mentioned that CosMx penetrated about 20% of the GeoMx installed base. How much runway for cross selling is there left? What is your target in terms of current installed base having both instruments?
- Longer term, do you envision reversed cross-selling, meaning new to NSTG customers first acquire CosMx and then expand to GeoMx?
- You have over 100 CosMx orders to date, above your expectations. As you are starting to ship those orders out, do you anticipate to have enough manufacturing capacity? What should we expect in terms of fulfillment of those 100+orders in 4Q

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and 2023?

- You anticipate to have about \$30M in pre-orders for CosMx for 2023. Assuming you will be able to fulfill those in 2023, do you expect to be able to fulfill new orders placed in 2023 in the same year?
- In Situ technologies has a growing number of competitor entrances. As you are having conversations with potential customers, and what are you hearing from them in terms of picking your system vs competitors'? What do you view as your key competitive advantages?

nCounter

- Obviously, the aging installed base has recently become an issue that negatively impacted your pull-through. What do you estimate your long-term pull through to be for nCounter given recent dynamics?
- To what do you attribute the slowdown in European academic research demand for nCounter?
- You mentioned that in 3Q the number of new nCounter systems placed approximately equals the number of older nCounter systems being inactivated, as such impacting both the instrument growth and pull through. Have you seen similar dynamics in 4Q so far? Do you anticipate these dynamics to continue and perhaps deteriorate nCounter revenue long term?
- For the recently installed nCounters, how long does it take for the consumers to reach steady state consumable pull-through rate?
- What actions are you taking to improve the new instrument placements and consumable pull through? Or should we just think of nCounter as entering a cash cow phase?

Business model

- Given your FY23 guidance, what are some sources of upside and downside?
- How are you allocating capital between nCounter, GeoMx, and CosmX? What's the margin profile of each instrument?
- How do you view M&A opportunities in the current market, and what are you looking for in terms of potential targets?
- Last quarter, you announced some cost reduction initiatives on head count. Given the current macroeconomic environment, do you anticipate any additional cost reduction initiatives?

Pacific Biosciences

The company issued long-term guidance at the recent Analyst Day. Focus is on Revio order book since launch and puts and takes for the 2023 outlook in light of the Revio launch and macro headwinds.

End Markets

- What's the updated mix looking like between different applications including Popseq, human genome, plant and animal, and how does that compare to your expectations?
- You are confident in the potential of true long reads in human genetics, especially in WGS for rare and genetics disease diagnostics and transcripts isoform biomarkers. What needs to happen for these applications to scale up in clinical? What is the expected time line?
- What is your updated view on synthetic long reads? What applications do you think can be sufficiently done using synthetic long reads? What percentage of those applications will be converted to true long reads now that the cost has dropped to \$1,000/genome?

Long Read

- How should we think about Revio order book to date? How does the order book to date compare with your expectations?
- You mentioned the annual pull through of Revio will be “multitudes” of Sequel II/Ie. How should we think about the consumable ramp of Revio vs. Sequel II/Ie?
- What does the current customer distribution for Revio look like? Which customers will keep using Sequel II/Ie, and how should we think about the pace of transition in existing customers?
- What are your thoughts on the macro headwinds on the Revio order funnel in 2023 given the price tag?
- You are developing an ultra-high-throughput long-read sequencer for the high-end market as well as a bench-top long-read sequencer for the low-end market. Could you give an update on the progress so far and/or expected launch dates? How should we think about these new products in terms of value proposition and synergistic integration with current offerings?

Short Read

- What percentage of the LBx TAM can benefit from the best-in-class accuracy of Onso? How should we think about the cost and justify it? What are some possible bottlenecks for broader adoption of Onso?
- How should we think about the attach rate between Onso and Revio?
- What is the expected time line for throughput scale-up for Onso? Could you provide any updates on the next-generation high-throughput SBB sequencer that you are current developing?

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Operating Model

- How should we think about the cadence of OpEx increase in 2023 given the new product cycles and sales force expansion/incentives?
- What are the margin implications from the new product cycles in 2023?

Seer

Focus is on demand trends in light of biopharma funding environment, timing of external validation data publication to support broader adoption, and the competitive landscape.

End market

- As the proteomics market continues to grow, how is SEER competitively positioned? Are you running into any particular competitors more often than others?
- When do you expect high-plex proteomics to enter the clinical market more broadly? Other than throughput and costs, what are some possible bottlenecks for broader adoption of proteomics in clinical?
- Multi-omics is getting stronger momentum in LBx development. Do you plan to enter partnerships with LBx companies to incorporate protein markers into those tests?

Product

- How has traction been for Proteograph Analysis Suite 2.0 (PAS 2.0) since its launch? How quickly will we see impactful publications and discoveries from using that platform? What publications should we look forward to in 2023?
- What feedback have you received from early adopters of Proteograph Analysis Suite 2.0 (PAS 2.0)?
- How quickly can we see a meaningful impact on revenue from Proteograph Analysis Suite 2.0 (PAS 2.0)?

Commercial

- How quickly do you expect a typical customer to scale up their research? Where do you think the costs need to go for customers to scale up meaningfully?
- What is your latest customer mix (academic vs commercial)?
- Is your target of 60% academic and 40% commercial largely driven by the macroeconomic environment, or is this a long-term strategic goal? If a long-term strategic goal, why?
- Do you continue to see a much longer sales cycle for academic, or has the situation changed?
- When do you expect the elongated sales cycle to normalize? How is your sales force motivated to address this issue despite the impact from macro headwinds?

Operating model

- How should we think about 2023 revenue? What are potential sources of upside and downside?
- What is your long-term gross margin potential, and what levers can you pull to improve gross margin? What are some incremental sources of gross margin other than volume scale up?

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Singular Genomics

Focus is on progress update on manufacturing hiccup resolution, early customer feedback on the G4, and management's plan to sustain customer demand in light of growing competition.

General/Operating Model

- What are the latest updates on the manufacturing delays? Do you have an expected time line to share with us? Which aspects have improved or deteriorated?
- Were you able to locate alternative vendors, or are you still utilizing in-house manufacturing?
- Given the manufacturing issues, can we still expect the early access program of PX in late 2023? Or has there be a further push? Also in terms of specs, what are the main technical milestones that remain to be achieved at this point?
- How should we think about revenue and cash burn in 2023? Can you give us qualitative color especially given the number of moving pieces (manufacturing issues, G4 placements, sales build-out).
- Due to macro challenges, OMIC slowed opex growth to extend cash runway. What other levers are at your disposal to aid in cash preservation if needed?

Product

- What feedback are you getting from early customers of G4?
- What are your expectations for G4 placements in 4Q and 2023? How does your current order book look, and how does it compare to your expectations?
- What are your estimates for the potential consumer pull through for G4? What is your estimated ramp time line?
- What is the latest launch time line for the G4X4 system?

Commercialization

- What is your latest breakdown of your customer base? Is it still two-thirds biopharma? What is your long-term customer mix goal and why?
- Due to biopharma spending cuts, you now offer lease arrangements. How has the traction of leases been so far? Are you seeing increased interest from customers who were significantly impacted by the macro environment?
- How are you prioritizing your go-to-market focus? Which customer segments are you prioritizing in the near term, medium term, and long term? How large is the potential installed base opportunity within each segment?

Competition

- Given that ILMN continues to reduce prices from current levels, how much buffer do you have to stay cost competitive for users?
- In addition to ILMN, there are a number of new entrants (such as Pacbio, Element Biosciences). What's your view on the latest competitive landscape?
- Now that you encountered a setback and lost a bit of your head start, what are some

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of the most durable advantages of the G4 platform?

- TXG's Chromium X enables high-throughput single-cell analysis. How will the cost per sample on PX compare with the Chromium X? What other competitive advantages do you anticipate PX would have over its competition?

10x Genomics

The company did not issue long-term guidance at the recent Analyst Day. Focus is on Xenium early order trends (although the company will likely not quantify), expectations for recently launched new products, and qualitative comments on 2023 outlook in light of macro headwinds.

Overview

- Give us an update on your current customer mix between academic and biopharma. How do you see that mix evolving over time, especially given your recent and upcoming product launches?
- As the cost of sequencing continuously drops driven by recent ILMN actions, are you seeing customers allocate more budget toward single-cell and spatial genomics?

Single-cell

- With price elasticity being the pivotal factor here, how do you expect it to play out in the next couple of years? How much incremental demand do you think will come from existing customers running larger studies vs. new customers onboarding?
- For those who have yet to adopt Chromium even after the launch of Chromium X and the number of new features, what's the outstanding hurdle?
- Can you share the latest developments and early traction of Flex and Nuclei Isolation kits? What feedback are you hearing from your early customers?
- What's your current funnel mix between Chromium Controller, Chromium IX, and Chromium X? How should we think about the number of addressable customers for Chromium X? How much interest in Chromium X are you seeing from biopharma?
- Following the November commercial launch of BEAM-ab and BEAM-T, what can you tell us about early customer interest?
- Translational use is driven by biopharma. How do you plan to expand your biopharma penetration?

Spatial

- Do you have an updated time line to share with us regarding Visium HD?
- Have you observed any customer holdout on Visium prior to Visium HD launch, especially now that Visium HD is pushed out?
- What feedback are you getting from your early customers of Visium CytAssist, and what is your current pull-through vs target?
- In 3Q, TXG sold 100 Visium CytAssist instruments. How many instrument orders for Visium CytAssist have you received in 4Q, and how should we think about the placements into 2023?
- For Xenium, what feedback are you getting from early customers? How many instruments have you shipped so far? What is your target for next year, and how should we think about Xenium ramp up relative to your other products?
- For Xenium, what is your anticipated customer mix (by type academic vs pharma), and do you expect the demand to come from TXG's existing customers vs new

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customers?

- Which products currently on the market or to be launched in the near term do you view as Xenium's competitors? What are the key features that differentiate Xenium from competitors?

Business Model

- How should we think about revenue growth next year. What are the possible sources of upside and downside?
- How should we think about GM trends? What accretive and dilutive factors are at play, and what's your long-term GM target?
- In 2Q22 you appointed a new CCO to focus on commercial turnaround. What has been achieved to date, what are the main challenges, and what remains to be done in this turnaround?
- On the analyst day, TXG mentioned a cash flow breakeven target of YE2023. What are the main drivers of reaching that target, and what do you anticipate the challenges could be? Xenium is expected to be margin dilutive. How do you balance Xenium placements with the cash flow breakeven target?

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Company Profiles

Genetic Diagnostics

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Adaptive Biotechnologies

Focus is on 4Q MRD volume trends, initial 2023 outlook for MRD, new guidance approach to MRD pharma milestone revenue, and any upcoming milestones for Immune Medicine drug discovery.

Margin, Capital Structure, LT guidance and general

- How should we be thinking about 2023 for MRD and pharma revenues? Any qualitative feedback you can give us? The Street estimates 18% growth next year for ADPT. How do you feel about that estimate?
- Given the long-term guidance of 20-30% revenue CAGR, what are the main drivers of revenue within each revenue segment? It was previously mentioned that MRD would be higher in the near term and later Immune should accelerate. What is behind that expectation?
- In your long-term outlook do you incorporate a weakening global economy? Do you anticipate a softening in 2023 or meaningful fluctuations in growth trajectory? And what indicators or factors do you see so far that may cause you to be more optimistic or conservative about next year?
- Related to the pharma side of the business, could you share if you are seeing any impacts from the weakening global economy? Are there any leading indicators or anything of that nature that you have noticed that look concerning or indicate softening, specifically as it relates to biopharma funding?
- The EBITDA breakeven target depends on your ability to drive OpEx leverage. You previously stated that real estate consolidation, workflow enhancements, reduced sequencing costs, and S&M and G&A improvements will be key to driving OpEx leverage. As of 3Q you were on track with these cost-cutting actions. As you look at Q4 and 2023, what do you anticipate to be the main hurdles in achieving your target cost-cutting initiatives, and how do you plan to overcome them?

MRD/ClonoSEQ Clinical and Pharma

- How should we think about MRD volume and ASP in 4Q, and what dynamics do you anticipate can either accelerate or decelerate these volume and ASP trends in 2023?

MRD Clinical:

- Could you comment on contribution from new accounts vs repeat customers in 2022 so far? What is driving each piece, and how does it compare to your expectations? Which of these two customer segments do you focus most of your attention on as you chase growth?
- What are your most up to date penetration levels for ClonoSeq, and what are your long-term targets? What is your strategy for reaching those targets?
- It was noted that now about 30% of ClonoSeq volume is on blood and that further conversion would increase frequency of tests. What about the ASP? What type of impact should we be thinking about as you further convert from bone marrow to blood MRD?

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- In 3Q clinical volumes grew 52% y/y. What were the key drivers of that growth, and do you continue to see similar trends into this quarter?
- You mentioned that ASP is now about \$1000, and it is expected to grow mid single digits. Could you elaborate as to what are the push and pull dynamics on the pricing?
- Can you expand on the penetration of academic centers vs. community setting this quarter so far. How does that compare to your expectations and ongoing trends?
- Regarding the Medicare coverage for MRD in DLBCL (75% of patents are Medicare aged), what are the key hurdles in the process toward revenue ramp up? Have there been any surprises, or has the process been similar to historical processes for other diseases or even perhaps accelerated?
- Related to ClonoSEQ, previously it was shared that an average sales cycle is about nine months to activate an account and two to three months for the first patient ordering. Have you seen any improvement on that front? Can you share updated numbers with us?

MRD Pharma:

- It was mentioned on the 3Q call that almost every major pharma company currently developing a blood cancer drug is using ClonoSEQ in some capacity. So, as we look towards the next few years, can we continue to expect similar or increased penetration with existing clients but not from new accounts? Or do you anticipate other pharma companies to start developing blood cancer drugs? How much penetration runway do you think is left with your existing clients?

Immune medicine

Pharma:

- In 2Q, you announced a change in strategy for T-Detect toward pharma partnerships in the near term. Do you have an updated time line to share on the commercialization of T-Detect? Longer term, should we anticipate first a launch of T-Detect for specific diseases and then T-Detect as a single blood test for various diseases? How should we think about that?
- What's your current penetration in clinical trials? What are main drivers of increased adoption, and what are your long-term penetration targets?
- Have you noticed any changes in the 2H of 2022 in terms of lab activity levels with research customers?

Drug Discovery:

- As of the 3Q call ADPT is on time to deliver three TCR candidates for Genentech. Is there an update related to these TCR data packages, and what is your outlook or target for 2023? And how should we think about milestones related to those candidates?
- What are the time lines for the next milestone from Genentech, and what additional steps have to happen on your end to secure the payments?

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Guardant Health

The company recently read out headline results from the ECLIPSE trial. Focus is on timing of stage-specific performance data release, progress in FDA submission, the possibility of FDA panel prior to approval, and SHIELD volume trends in 4Q. Investors will also look for an update on G360 OUS expansion and volume recovery as well as the road map for Infinity.

SHIELD

- How did SHIELD volumes trend in 4Q?
- Given the recent ECLIPSE results, what time line can we expect for stage-specific performance data releases?
- How far along in the FDA submission process are you? Are you on track for 1Q23 submission?
- How likely is the possibility of FDA panel prior to approval?
- What do you think is the bar for AA performance for a blood-based test? What do you think is the theoretical maximum potential AA performance for a blood-based test?
- You expect ACS guidelines to drive meaningful uptake of SHIELD before USPSTF guideline. Walk us through the time line of implementation here. How quickly do you expect private payors to initiate and implement coverage after ACS guideline?
- You previously talked about 60% LT GM for SHIELD (assuming \$500 price point and \$200 cost). Does that long-term margin profile still hold as SHIELD evolves into a multi-cancer screening test over time? What does COGS look like for next-gen multi-cancer SHIELD, and how future-proof is the \$895 pricing?
- What are your expectations on the competitive takeout for compliant population (currently using stool-based or colonoscopy screening) vs. blue ocean of non-compliant population (not using any screening)? How quickly can we see a meaningful impact on revenue?
- Is your current sales force enough to support revenue ramp in 2024 once ACS guideline is in place?

REVEAL

- How has traction been for REVEAL in terms of volumes since launch in breast and lung in August? When do you expect to release data on additional indications?
- When do you expect to get coverage for CRC in the surveillance setting?
- When do you expect to get coverage outside of CRC?
- How significant do you view the expected NCCN guideline endorsement for MRD in CRC?
- What's the road map for getting ADLT status? What kind of additional data is required? What's your expected time line? Where do you think pricing can go with ADLT status?

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New products

- Could you discuss the time line and plans for INFINITY to be used in clinical? What do you think will be the biggest bottleneck for INFINTIY to be adopted in clinical?
- What's the ASP of Infinity and how to think about long-term ASP trend of biopharma volume (currently \$3,600)?

G360 franchise

- How should we think about the weakness in the US this year? How much of it can be attributed to macro headwinds, and how much can be attributed to competitive pressure?
- Is there a way to quantify the OUS ramp of G360 CDx in Japan and EU? What other geographic regions you are planning to target?
- How much volume are you generating from Response now? What's the attach rate to G360? What's your target?
- When do you expect to get CMS coverage for Response?

General/Operating Model

- How should we think about revenue in 4Q and 2023, and what are potential sources of upside or downside?

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Invitae

Focus is on 4Q clinical volume trends, turnaround execution progress, stability of retained businesses, timing of potential guideline expansion for germline testing. Investors will also look for any long-term strategy to drive profitable growth.

Germline Oncology

- A large percentage (~40%) of your revenue is generated from the germline oncology segment. If you think about the long-term trajectory of that business in terms of revenue growth, what do you envision and what evidence do you have to support that?
- RNA and polygenic risk score: Approximately one year ago you decided to re-launch RNA and polygenic risk score. Is there an update on the progress of the launch, and if so, can we expect an incremental revenue ramp?

Somatic Oncology

- ArcherDc/ PCM MRD product : What is your competitive positioning?
- Also, regarding the road map for MRD (FDA), it was mentioned last year that it should take about three to four years. Is that time line still on track?
- Long term, do you see significant synergy opportunities between Archer MRD product and the remainder of your oncology business? If so, do you have a rough CAGR estimate that you are targeting, and what do you think are the main synergy opportunities?
- There is a lot of talk about the future of oncology being early cancer screening to identify who is at elevated risk of cancer. Is there a long-term goal of entering that space as well, or do you intend to focus on therapy selection and MRD?

Reproductive Health

- Given some of the business exists due to restructuring, how should we think about ASP increases following the exits within each business segment?

Rare Disease & Other

- As you think about rare disease and other segments of your business, what are the most incremental opportunities you see in the next two to three years?

Financial

- With regard to your long-term growth targets of 15-25%, how much of that do you anticipate to be organic vs inorganic growth? Even post restructuring, leaving you with healthier businesses, you are in a very competitive market. So what factors did you consider when you put out that target? Within the genetic testing market are you aiming at keeping your existing share, or are you hoping to gain market share?
- Since the announcement of the restructuring M&A has not been ruled out. Given the current market environment, how do you view M&A opportunities—as an opportunistic environment or more conservative focused on cash preservation?

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- Given the cash burn reductions, how much of the reduction is due to R&D cuts if any (including head count). And what are your R&D priorities for the next two years?

Restructuring

- Given that you are exiting the distributed kits business, do you not see the potential of distributed testing model? What are the advantages and disadvantages of this model, and for what areas in healthcare do you see long-term potential?
- Overall, the business divestitures and consolidation of geographies look like necessary actions given the current capital market conditions, but do you think that long term you would need to be re-entering those markets? What were the puts and takes that went into those decisions?
- Stepping back, given the leadership transition and restructuring, what impacts have you noticed on the culture of the organization (both positive and negative)? Have you experienced increased head count turnover since the announcement of the strategy?

Citizen acquisition

- Regarding your progress toward genome management long-term strategy and how Citizen plays into it, what are the main hurdles in developing and scaling a two-sided market place in the healthcare space? You have now launched Invitae Digital health. How are your conversations with clients transpiring, and in terms of initial client feedback, what can you share?
- How do you think about competitive dynamics in digital healthcare data management? Who are your main competitors, and what are the key competitive advantages of Invitae Digital Health?

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Myriad Genetics

Focus is on commercial turnaround execution progress, upside/downside to 2023 guidance, and expected contribution from new product launches.

General (LT outlook, model, margins and capital structure)

- During the most recent analyst day, you guided to +9-12% revenue growth in 2022-24. Given the time lines of new product launches, delays in rollout of commercial initiatives, and current macroeconomic backdrop, how confident are you in being able to achieve that 9-12% growth target? What are the potential sources of downside and upside?
- Looking into the 4Q and 2023, given the Covid cases declines but more challenging macroeconomic environment, can you discuss what you are seeing in terms of volume and pricing so far and what push and pull dynamics are playing out?
- You have proven the potential of your commercial strategy revamp with GeneSight. How confident are you that you can replicate that strategy to other segments of your business. What are the main hurdles in the strategy replication?
- Which business area are you focusing your attention on next in trying to replicate the commercial strategy used with GeneSight (more effective and scalable sales and marketing model)?
- How are your key performance indicators trending since the Analyst Day in August (such as employee turnover, employee engagement, total turnaround time, net promoter score, total active customers trends and demand volume trends, COGS per Test)?
- What are the time line updates on the two new facilities in the Bay Area and Salt Lake City, and how do they compare with your initial expectation?
- You targeted 100-150 bps expansion in long-term margins during your Analyst Day. So far, you have been on track except for the most recent quarter. Can you discuss your confidence in hitting that target given the current inflationary and FX environment?
- Regarding your Getaway Genomics acquisition announced on Nov 1, do you have any updates to share with us regarding expected synergies?
- In terms of M&A, what are your current areas of focus as you look for additional deals? Are there interesting opportunities in the pipeline? How do you view overall M&A in the current macro environment.

GeneSight

- Can you talk about the competitive landscape in mental health testing. Who do you consider your main competitors in the space, and what do you hear from customers with regard to their preference of one product over the other?
- Given the improvements in volumes for GeneSight, how should we think about these metrics going into 2023? What are the tailwinds you in terms of volumes, and how should we think about pricing given the inflationary environment?

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Oncology

- How should we think about the testing volume for Hereditary cancer over the next 12 months given that volume stabilized last quarter?
- Regarding the MyRisk pricing, last quarter it was mentioned that MYGN received CPT code 81479 providing pricing of \$1,743. How does this pricing compare to your expectations? Given this, how should we think about the average ASP over the next 12-24 months?
- How has the competition changed in the last year? In which business segments do you see the most competition or the most change? How do you view competitors such as NVTA?
- How should we think about volume and ASP trends for Prolaris, EndoPredict, and MyChoice CDx. What are the near-term headwinds and tailwinds?
- Do you have revenue ramp targets for Precise Liquid? How should we think about the launch next year?
- What do you consider the competitive advantages of Precise Liquid over existing products on the market?
- How should we think about the time line for MRD product? Are you on track with the commercial launch to happen in 2H2024, and how do you envision revenue ramp to happen?
- What do you consider the competitive advantages of MRD product over existing products on the market?

Women's health

- Can you discuss competitive dynamics within the Women's health business? Specifically, how are you competing against players like NVTA and NTRA? Also, what do you consider your advantages over your competitors?
- How should we think about the growth profile within the women's health business over the next 12 months excluding the First Gene and Gateway Genomics. What are some of the main tailwinds and headwinds affecting the business?
- During the Analyst Day you put out the target contribution for growth for Women's Health including First Gene in the range of 3-4%. Given the Gateway Genomics acquisition, can we expect higher growth following the acquisition? What is the expectation there, and how should we think about it?
- So you expect to launch First Gene in 2H of 2023. How should we think about the penetration of the product, and when can we expect incremental revenue ramp? Do you think it would be a similar trend to historical launches, or do you anticipate accelerated ramp? And related to that, do you anticipate First Gene to replace your current Women's health offerings such as Prequel and Foresight, or do you expect it to be more of a complementary product?
- What products currently on the market or in the pipeline do you consider direct competitors of First Gene, and what are your competitive advantages?

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Natera

The company recently reported positive ACOG updates for microdeletion. Focus is on management's latest timing expectations for pending guideline expansions (microdeletion, ECS, MRD), Signatera volume trends in 4Q, and any updates on NIPT billing investigations.

Oncology

- How should we think about Signatera's volumes in 2023?
- What is your opinion on tumor informed vs tumor naïve MRD? Do you see long-term applications for both? What is your view on NVTa's possible entry into the space with a tumor-specific product? What do you view as your competitive advantage apart from being a first mover?
- Could you share some color on the mix between clinical vs biopharma volume year to date? What are the key developments shifting the mix, if any?
- Within oncology, next year NCCN guideline endorsement is expected. Do you have any updates on the timing of the endorsement? What else remains to be done to get this expected endorsement approved?
- Internally, do you have a list of other potential guideline endorsements or potential reimbursements that you are targeting to obtain in the near term?
- What was the rationale for developing an IVD kit version of Signatera?
- How do you balance the margin pressure due to Signatera's non-covered indications with limiting volume for uncovered indications? What are the puts and takes there?
- You have previously mentioned that you are on track with the cancer screening development road map and expect to share early validation data in early 2023. Are there any updates regarding the progress that you can share with us? Also, compared to your previous product development time lines do you anticipate this process to be accelerated or similar to historic trends?
- How is NTRA's early cancer screening technology differentiated from competitors? How do you plan to enter the market given that you will not be a first mover in the space?

Women's Health

- On the 3Q call, you mentioned that the NIPT market is about 45-50% penetrated. What are your current estimates for high-risk vs average-risk NIPT penetration? What is your overall target penetration? What are the main challenges to increasing penetration rates above current levels?
- As you are closer to the microdeletions guideline endorsement, especially given the recent positive ACOG updates, what are your latest timing expectations? How significant do you expect the guideline endorsement for microdeletions is going to be?
- Regarding the guideline endorsement for microdeletion, what are your target penetrations and target ASPs vs current levels? How should we think about it in 2023 and 2024, and what are the key hurdles in achieving your target penetration and target ASP?
- Which products if any do you consider direct competitors of your product, and how

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you differentiate?

- 2021 and 2022 saw competitor exits and restructuring. Can you give us an update on the latest market share dynamics? How much share have you gained over the last year, and how sustainable is the share gain?
- What is the latest update regarding CA program injunction? When can we expect a meaningful improvement or resolution?
- Have there been any additional regulatory inquiries regarding the NIPT billing practices? Or should we consider this issue resolved following the latest update on the 3Q earnings call?

Transplant

- What are the recent dynamics in the transplant market that you view as concerning?
- What are your current penetration estimates and long-term targets within transplant per indication? What are the main challenges to reaching your penetration targets?
- Following the expansion into heart and lung, what are your initial thoughts on the difference in ramps for heart and lung vs kidney?
- Do you have plans for additional organs? If so, which ones are you targeting? How far along are you in the development process?
- What is your opinion or response to the Noridian/MoIDx CAC review of ctDNA-based transplant organ rejection testing? Do you disagree with their opinion of possible overutilization?

Operating model

- What are the main drivers from the COGS perspective of reaching cash flow breakeven target by 2023?
- Given the expectations of multiple guideline endorsements to happen starting 2023, how much of the incremental ramp from those endorsements is incorporated into your 2024 cash flow breakeven target?
- How confident are you in reaching the mid-2024 cash flow breakeven target given the reliance on many moving parts (such as GM improvements, multiple guideline reimbursements) and the overall weakening macroeconomic environment?
- For 2023, the Street has you growing revenues 21%. What do you think about that estimate, and how achievable do you think it is?

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Sophia Genetics

Focus is on customer retention and utilization trends in 4Q, expected macro/FX headwinds in 2023, and any near-term progress to watch for in terms of US market and biopharma penetration.

Clinical business

- How do you expect revenue and ASP to trend in 2023 given the macro headwinds, especially FX and customer funding constraints?
- How big is the market opportunity for CarePath? What is the customer feedback so far? Beyond NSCLC, what other indications are you looking at?

Biopharma business

- How should we expect the adoption ramp of DDM/CarePath in biopharma compared to clinical?
- You mentioned the oncology portfolio (i.e., HRD testing) saw the biggest growth this year. How should we expect the ramp of HRD in 2023?
- Moving forward, how will you target biopharma and clinical customers differently? What are their preferences in DDM applications, and how do you address their demand differently? What are your expectations of exposures?
- When can we expect additional readout from the Deep-Lung IV study?

Partnerships

- How significant will the revenue contribution be from partnerships with MSKCC and Boundless Bio? What are the margin implications?
- What synergistic value do you prioritize when choosing potential new partnerships?

Commercial

- What product/application in your portfolio has attracted the most new customers?
- Compared to a year prior, what does your current customer base look like in terms of geography? And in terms of clinical vs. biopharma? How should we expect the ramp of new customers in each segment?
- How much is the US market contributing to revenues? How should we think about the penetration pace in the US market in 2023? What about other regions of the world?
- Which geographic areas do you view as underpenetrated and thus presenting the biggest opportunities for SOPH?
- What would drive a customer to use more DDM applications? What new applications have customers requested the most?
- What do you view as SOPH's normalized churn rate? Do you anticipate churn rate to be higher in the near term? If so why?

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Operating Model

- How should we think about GM next year? Do you anticipate any near-term swings given macro headwinds?
- During the 3Q call, you pointed out moderating R&D and capital spending. What other levels do you have to aid in cash preservation if needed?

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AbSci

Focus is on new project pipeline in light of biopharma funding environment and any upcoming milestones in 2023 to support near-term revenue visibility.

General/Technology

- Given your expertise in AI and your value proposition, who do you consider your closest competitors in the space? And how do you differentiate yourself from those competitors?
- If you look at your current and potential partners (mostly large pharma and biotech), what would you say is your current vs target long-term penetration rate? Also, what do you estimate your TAM to be?
- What is your long-term target mix between various partners? Such as biotech vs large pharma? What are the factors you are considering when setting those targets?
- Regarding your AI capability, where does it stand today, and how much of your workflow is handled by humans vs AI? When do you expect AI to take over fully?

Project outlook

- What is your expectation for the 2023 new project mix between discovery and cell line development?
- How should we think about 2023 new deals signed given that you did 10 this year? What are the sources of potential upside and downside?
- How should we think about milestones in 2023? What quantitative or qualitative information can you share with us, and what are the main drivers of those milestones?
- On the discovery projects, you stand to realize greater upside in the long term, but the probability of success is lower. What are your most recent estimates for the probability of success on those early discovery projects? What actions/steps do you anticipate would increase the probability of success in the near term and in the long term if any?
- You have mentioned that in your discussions with large pharma you are aiming to get more up-front payments to aid in near-term revenue. How are those discussions going, and what does that mean for the back-end revenue opportunities? What are the puts and takes in that decision on prioritizing near term vs potentially higher long term?
- Regarding your partnership with Merck, when do you anticipate all three drugs targets to be elected? You previously mentioned that you are on track to have one elected in 2023. What are the main challenges in that process from your perspective?
- Have you been able to convert any biopharma companies that are currently using mammalian cell lines or other alternatives to your e.coli system for new drug development? What are the main challenges in this conversion?
- When looking for new partners, what are your criteria? Are you looking for a specific size, focus? From your currently active deals, would you say ASBI reached out to them, or were there partners that reached out to you? How does the initial partnership discussion process work?

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- Looking at your capacity, would you say you have excess capacity or are you constrained? What are your nearest term unmet needs in terms of capacity?
- Given the current macro environment and as biopharma tighten their spending, have you noticed any reluctance or delays from biopharma companies regarding signing of new projects?

Operating model

- Most recently you lowered your cash burn driven by head count reductions and some capex cuts. As you think about 2023, what are your expectations for opex and capex? And how much embedded flexibility do you have left?
- Thinking long term, given the skewed project mix toward discovery projects and extended cash runway, what are your expectations in terms of breakeven time line and future financing needs?

Berkeley Lights

The company issued long-term guidance at the recent AD. Focus is on preliminary outlook for 2023 in light of the biopharma funding environment and execution plans around new products.

Commercial model

- What percentage of market adoption potential is locked by price of BEACON, and what percentage is locked by applications?
- What are the business implications of prioritizing high ROI projects like AAV and TCR in terms of visibility, pricing, cost structure, etc.?

New product

- How should we think about the adoption of BEACON SELECT compared to BEACON? What about the consumable utilization and pull through? What is the impact on margins?
- Since the announcement of BEACON Select, what have you heard from interested customers? Have you began taking pre-orders? Are you on track to launch in 1H23?
- You anticipate to launch Beacon One in 2H23. Do you have estimated pricing to share with us? What about consumable pricing or expected consumable pull through?
- Other than publications, what else needs to happen to drive adoption of BEACON ONE in academic?
- Since the announcement of the two lower priced BEACONS (Select and One), have you started to notice potential customer holdout on purchasing original Beacon and instead waiting for the lower priced models?
- Have you been able to secure any noteworthy academic partnerships to explore new applications on the Beacon platform?
- Given the current macro environment and its impact on biopharma funding environment, have you noticed delays or hesitation from potential biopharma customers with regard to purchasing new instruments? What about consumable pull through from existing biopharma customers?

Operating model

- How is the profitability for AAV development and TCR discovery compared to antibody discover?
- Regarding your recent merger, what are the key integration aspects you hope to accomplish within the first six and 12 months following the completion of the merger?
- During the merger announcement, you discussed at length cost synergies you hope you accomplish. You also mentioned that you hope to achieve some revenue synergies, but they are not accounted for in the \$70M expected synergies. Now that you are closer to the completion of the merger, do you have a clearer picture on what revenue synergies you can achieve? Can you share them with us?
- Given the management changes in the 1H22 and workforce reductions, what impact

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have you seen in company culture and morale? What about metrics such as employee turnover?

- You announced a turnaround road map in 2Q22. What has been achieved to date, and what else remains to be done? What were some of the main challenges you encountered?
- Given your recent acquisition, how do you view any other potential M&A deals? What, if any, areas of interest or gaps do you intend on filling?
- How has your recent merger change new product time lines?
- Given that the merger was announced after the Analyst Day, can we assume that the metrics and long-term targets announced at the Analyst Day did not incorporate IsoPlexis revenue and cash flow contributions?
- How should we think about GM target of 70% given the merger? What about recurring vs platform revenue mix targets?
- Can we expect a new reporting structure post-merger?
- What are your most recent capital allocation framework and main priorities?

Catalent

The company recently lowered FY23 guidance significantly with FIQ results. Focus is on project booking trends for both Biologics and PCH and management's plans to improve revenue recognition terms, revenue visibility, and cash flows.

End market and general

- Given the current evolving macro environment, what are the latest dynamics you are seeing with the regard to your PCH segment in terms of customer discretionary spending and inventory destocking and with regard to you biologics segment in terms of customer budgets and R&D pipeline activities?
- What are the latest dynamics on the development stage projects for both biologics and PCH? Do you see continued cash preservation and pipeline prioritization happening, or has the situation normalized?
- How much has industry outsourcing rate and CDMO penetration increased post pandemic? Do you see such increase as permanent? What are the main drivers and considerations for sustaining the outsourcing rate?
- How much industry capacity has been converted post pandemic to non-Covid related projects? How much capacity do you think is yet to be converted, and how much do you think will remain Covid related in the near term?
- How much overall bioprocessing industry capacity has been added post pandemic for drug substance and fill/finish, respectively? How much supply/demand gap still remains for drug substance and fill/finish, respectively?
- As you look toward F23, what do you anticipate to be the main challenges for reaching your guidance, and what do you foresee as sources of potential upside?
- Given the recent dynamics, how do you plan on improving the revenue recognition processes? What has already been implemented if anything?
- CTLT had previously mentioned its desire to expand in Europe. How does the Europe demand profile differ from the US, in terms of drug modality, mix of biosimilars, pricing, etc.? How about the competitive landscape? Given the current macro environment there, have your plans changed?

Biologics

- How do you assess the risk profile of your Biologics pipeline? Can you provide any color on the Ph1/2/3 mix within your Biologics portfolio? How far ahead do you have visibility into the biologics business, especially the development programs?
- The recently lowered FY23 guidance still suggests 30-50% non-Covid biologics growth. Given the biologics pipeline activity slowdown, how confident are you in achieving that 30-50% target?
- In light of the cell therapy pipeline progression delays you called out recently, what kind of time line should we be looking at now for your cell therapy capacity to reach full utilization? What are the implications in terms of continued margin dilution from the cell therapy business?
- The FY23 guidance assumes Covid revenue unchanged at \$380M. Can you give some color on the dynamics you are seeing that influenced your unchanged Covid revenue guidance?

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- You have several capacity expansion projects underway such as drug substance for cell and gene therapy, and drug product (prefilled syringes). How much of this additional capacity is already spoken for? Where might you see additional capacity need once your existing projects are completed?
- For future capacity expansion, what's your preference between organic investment vs. acquisition? How does your preference differ by drug category? What gaps are you looking to fill, if any?

PCH

- How far ahead do you have visibility into the PCH business? What's your expectation for PCH recovery?
- What drives Bettera's impressive +10% growth (F1Q23) despite challenges in the remainder of the PCH segment? How sustainable is that growth, and what are the key drivers?
- You have outlined macro headwinds impacting the PCH segment on the two sides as inventory destocking and consumer discretionary spending. What percentage of PCH revenue would you say is impacted by these trends the most? Also, what were the drivers of declines in prescription products?
- You have capacity expansion due to Metrics Contract Services acquisition, for high potent drug manufacturing. How much of this additional capacity is already spoken for? Where might you see additional capacity need once your existing projects are completed?
- You have mentioned that you expect synergies from the business combinations into PCH. What are those synergy estimates, and how much of that estimate has materialized so far?

Operating model

- What do you view as key sources of upside/downside to your +8-12% long-term organic growth target?
- You're currently holding more than double the normal inventory level. How quickly do you expect to implement inventory normalization?
- Can you expand on your capital deployment model. What are your priorities? Have they changed given the current macro environment? You recently lowered your Capex expectation. How are you balancing priorities?

Repligen

The company recently issued a preliminary 2023 outlook of +16-20% growth with 3Q earnings. Focus is on latest industry de-stocking and order normalization status and any upside/downside risk to Street numbers for 2023.

Macro headwinds

- How should we be thinking about the 2023 guidance initially announced at the 3Q call? Should we still expect the base business to grow in line with the long-term range of +15-20% organic, with COVID of \$30-40M along with a \$25-30M FX headwind? What are potential sources of upside and downside to this guidance?
- Although 2023 COVID contribution is guided down to \$30-40M, what could further drive the upside or downside of this number?
- You previously mentioned it may take four quarters before ordering patterns normalize. How should we think about the magnitude of remaining headwinds compared to what we've seen so far? When do you think we will see a trough in the inventory before recovery? And how does this differ from the 2017/2018 time frame?
- What are the trends in Asia vs. EU vs. US as more manufacture facilities open up? How should we think about the sustainability of that growth?

Base business

- How should we think about the expected +16-20% growth for 2023 base business against +33-34% in 2022? What incremental factors could bring the number up or down other than COVID and FX headwinds?
- For the chromatography business, what do you think the resin availability situation will look like in 2023?
- How many of your existing customers do you expect to convert to platform accounts? How many of your new clients will join as platform accounts?
- What is the book-to-bill trend in 2023 for both the base business and overall?
- As more novel therapeutic modalities enter clinical trials, did you notice any significant changes in customers' demands or order mix? What new trend have you recently noticed? How would RGEN differentiate itself in accommodating those new demands?
- Biosimilars of Humira are expected to enter the market in 2023. How do you expect biosimilars to ramp up riding that wave? When can we expect this wave of biosimilar to have a meaningful impact on RGEN's revenue/product mix?
- Could you talk about your product lines related to cell and gene therapy? What are the key products that you're providing for that market? Any plan to add new or customizable product offerings?
- What is the latest update on the integrated Fluid Management division that is expected to contribute \$200M in revenue by 2027?

Operating model

- Inflation pressure in the mid to high single digits is expected in the current market.

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What type of strategies is RGEN is using to offset inflation pressure? How should we think about pricing moving forward?

- How much will COVID roll-off and macro headwinds flow through the P&L? What is your expectation of the margins in 2023?
- What levels do you have at your disposal in case of worsening macroeconomic conditions next year?
- What is your stance on M&A in these market conditions? If you are interested, what areas are you looking to fill?
- How should we think about GM in 2023 and long term?

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EXHIBIT 51

Life Science & Diagnostic Tools: Diagnostics

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INVITAE CORP

EQUITY RESEARCH

July 26, 2022

Price: \$2.14 (07/25/2022)
Price Target: \$2.50 (Prior \$8.00)

MARKET PERFORM (2)
FROM OUTPERFORM (1)

ESG SCORE: 65/100

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Key Data

Symbol	NYSE: NVT
52-Week Range:	\$32.19 - \$2.13
Market Cap:	\$490.7MM
Net Debt (MM):	\$853.9
Cash/Share:	\$(3.01)
Dil. Shares Out (MM):	228.5
Enterprise Value (MM):	\$1,342.8
BV/Share:	\$12.43
Dividend:	\$0.00
Yield:	0.00%

FY (Dec)	2021A	2022E	2023E
EPS			
Year	\$(2.95)	\$(2.95)	\$(1.97)
Prior Year	-	\$(2.93)	\$(2.00)

Revenue (MM)			
Q1	\$103.6	\$123.7A	-
Q2	\$116.3	\$136.0	-
Q3	\$114.4	\$126.8	-
Q4	\$126.1	\$133.4	-
Year	\$460.4	\$519.8	\$520.1

RATING CHANGE

**DOWNGRADE TO MARKET PERFORM:
REFINANCING TIMING/UNCERTAINTY CAPS
UPSIDE**

THE COWEN INSIGHT

We downgrade to Market Perform following additional insight on the path forward to refinancing the '24 debt maturities. While we expect the \$135M loan & \$350M convert can be refinanced, the timing, uncertainty around the mechanism, costs/dilution & default potential are likely to cap the stock, limiting follow through from the new plan ([here](#)) recently presented by the new CEO & existing CFO.

What's Changed?

We view the plan presented by the new CEO and existing CFO on 7/18 as a positive first step towards creating a path to reaching positive FCF. While the revenue growth rate was significantly reduced (from ~40% LT to new ~15-25%), confidence in the 40% had already waned materially following a series of shortfalls, plus the increasing view that material action needed to be undertaken to reduce the burn, which in turn meant cut investment/costs and reduce the growth rate. How management plans to handle upcoming debt maturities remained a key question, with the company indicating many potential options are being considered (though no clarity provided). Following initial release of the new plan, as we dug in further in the wake of the better burn outlook, our conclusion is the refinancing outlook has not improved. Namely, a restructuring was expected and was a step in right direction but the magnitude of the burn improvement (plus revenue reduction) did not create a material change. As such, despite our base case of successful refinancings, we expect the continued financing uncertainty and potential for meaningful dilution to serve as an overhang, capping the stock. We downgrade to Market Perform.

Coming Debt Maturities, the Burn, and Expected Cash Balances

Our updated model forecasts cash burn of (\$618M) in '22, (\$262M) in '23, (\$184M) in '24 and (\$87M) in '25. From a starting base of '22 YE cash & marketable securities balance of \$435M, we model cash at YE23 of \$174M, forecast a \$200M equity raise in '24 at \$2.50/share (to support ongoing burn/investment), enabling YE24 cash of \$190M and YE25 of \$104M. A critical assumption over the next three years is NVT successfully refinances its two 2024 maturities: the June 2024 \$135M term loan secured by a first priority lien, and the September 2024 \$350M convertible bond. Diligence reflects despite the detailed cost-cutting plan and a more focused growth strategy (from ~30-40% top line to 15-25%) enabling the better burn, the path to refinancing both '24 debt securities remains challenging. The '24 converts are quite illiquid and prices (post the new NVT plan) remained around 80% of par, reflecting this lack of improvement from the convert market. Beyond these two '24 maturities stands the 2028 \$1.15B convertible bond, which carries a 1.5% coupon.

Please see pages 4 to 11 of this report for important disclosures.

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AT A GLANCE

Our Investment Thesis

The high cost of genetic testing has limited incorporation into routine medical practice, though Invitae’s low cost strategy has supported rising test penetration across different indications. Invitae has tests in oncology, reproductive health, and rare disease priced lower than competitors that do not sacrifice quality or turnaround time. Future accessibility improvements, menu expansions, and patient data business can support share gains at the expense of specialty and reference laboratories offering single or multi-gene approaches, as well as drive broader market adoption of genetic testing. That said, we view the ability and ultimate structure of ~\$485M in debt due in '24 (plus looming \$1.2B '28 converts) to cap stock performance given a high uncertainty of new terms and ultimate refinancing potential, due in part to the high cash burn, competitive dynamics, and less willing capital markets.

Forthcoming Catalysts

- Progress/visibility on refinancing '24 debt
- Additional opportunity for restructuring (asset sales, cost cuts, burn reduction)
- Quarterly earnings report

Base Case Assumptions

- NVTA is able to refinance upcoming debt though at higher financing costs
- Revenue growth remains within the new 15-25% range

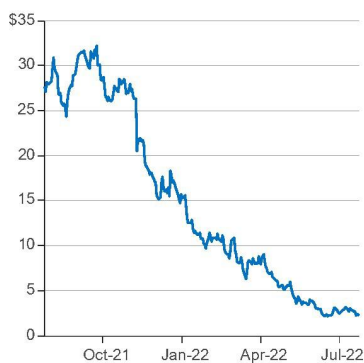
Upside Scenario

- NVTA gets to FCF positive faster via a combo of greater cost savings and asset sales
- Debt maturities are successfully refinanced
- Growth accelerates to 25%+ as the focus on narrower product set delivers greater impact combined with healthy end market trends
- Genome management and genome network services provide new sources of growth in the out years

Downside Scenario

- NVTA is unable to refinance the upcoming '24 debt maturities
- Revenue growth declines to <15% via share loss and price erosion
- Negative revisions to guideline or reimbursement decisions greatly impact NVTA test adoption
- LDT regulation concerns increase across pipeline products.

Price Performance



Source: Bloomberg

Company Description

Invitae is in the business of delivering genetic testing services, digital health solutions and health data services that support a lifetime of patient care and improved outcomes – from inherited disease diagnoses, to family planning, to proactive health screening to personalized diagnosis, treatment and monitoring of cancer. Invitae applies proprietary design, process automation, robotics and bioinformatics software solutions to expand the use and impact of genetic information and achieve efficiencies in sample processing and complex variant interpretation, allowing medical interpretation at scale.

Analyst Top Picks

	Ticker	Price (07/25/2022)	Price Target	Rating
Avantor	AVTR	\$30.83	\$44.00	Outperform
Danaher Corporation	DHR	\$273.38	\$340.00	Outperform
Thermo Fisher Scientific	TMO	\$567.44	\$693.00	Outperform

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Refinancings & the Stock: What Happens From Here



With prospects for refinancing the '24 debt securities not materially changed following the restructuring news, we no longer see NVTA's valuation multiple expanding as long as this refinancing uncertainty persists. How the refinancings occur will be a key factor in the stock price outlook following these deals. Our base case remains a senior debt structure replaces the existing one (though with more attractive terms to entice the refi), and similarly a new convert is issued with more attractive terms to refi the existing one.

We updated our model to reflect the terms/costs associated with current market conditions for these refinancings.

For the June 2024 \$135M term loan: This loan is secured by a first priority lien on all of NVTA's and its subsidiaries' assets, and is guaranteed by NVTA and its subsidiaries. We continue to assume the term loan is financed with another term loan during 2024, though we now reflect a higher cost loan replaces the existing one. The existing loan carries an interest rate of 3-month LIBOR (subject to a floor of 2%) + 8.75% (which today equates to ~11-11.5% all in range), and we assume the cost of the new term loan is 13%.

For the September \$350M convertible notes: The notes are senior unsecured obligations, and carry a coupon of 2% with a conversion price of \$29.74. We assume a new convert with more attractive terms (to the investors) is issued to pay down the existing convert, namely a 7.5% coupon with a conversion premium of 27.5%.

With the stock down at these levels, an intense focus on reducing the burn, ongoing cash needs to fund the operations and the \$1.15B 2028 convert obligations, the company is considering a variety of options to handle these financings. Issuing common equity can have material dilutive impact given the magnitude of share issuance required (while convert dilution also is potentially material assuming successful future conversion).

To provide support to the stock and to increase confidence in the business and aid the refinancings, management needs to better articulate NVTA's key products, market position, strategy, differentiation, and competitive trends. As well, establishing a new track record of quarterly execution against targets should be well-received.

Valuation: PT \$8 TO \$2.50

Our new PT is based upon ~2.5x EV/2023 revenues, in line with NVTA's current EV multiple (as we expect multiple expansion to be difficult given the financing overhangs remain firmly in place). Our prior PT used a P/S multiple of 3x, and we feel EV/revenues is more appropriate as it incorporates the debt profile in light of ongoing refinancing challenges.

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VALUATION METHODOLOGY AND RISKS

Valuation Methodology

Diagnostics:

Price targets are based on several methodologies which may include: analysis of market risk, growth rate, revenue stream, discounted cash flows (DCF), EBITDA, EPS, cash flow (CF), free cash flow (FCF), EV/EBITDA, P/E, PE/growth, P/CF, P/FCF, premium (discount) / average group EV/EBITDA, premium (discount) / average group P/E, sum of the parts, net asset value, dividend returns, and return on equity (ROE) over the next 12 months.

We make investment recommendations on certain early stage, pre-revenue companies based upon an assessment of their business model, technology, probability of market success, and the potential market opportunity, balanced by an assessment of applicable risks. Such companies may not be assigned a price target.

Investment Risks

Diagnostics:

Risks to the Medical and Life Science Tools sector may include: reduction or delay in research and development budgets and government funding, reduced or delayed purchasing from health care / hospital customers, increased or extended regulatory hurdles or processes for regulated products, increased dependence on volatile emerging markets for revenues and profitability, and general macroeconomic challenges.

Risks To The Price Target

Risks to the upside of our price target include faster than anticipated balance sheet clean up; faster than anticipated reduction in cash burn; and better than expected revenue growth, among others.

Risks to the downside of our price target include but are not limited to: customer adoption could be slower than expected; continued FDA uncertainty; reimbursement and clinical guideline hurdles; low visibility on financial trajectory, among others.

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ADDENDUM

Stocks Mentioned In Important Disclosures

Ticker	Company Name
AVTR	Avantor
DHR	Danaher Corporation
NVTA	Invitae Corp
TMO	Thermo Fisher Scientific

Analyst Certification

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The process begins with capturing unstructured data from more than 100,000 sources, in 14 languages. These data are culled from a wide range of sources with varied perspectives, including industry publications, news outlets, NGOs, trade unions, government sources, legal and regulatory filings, and academic publications.

Natural language processing is used to interpret semantic content from the original sources and generate analytics by applying criteria consistent with established sustainability and ESG frameworks. Performance is scored on a 0 to 100 scale. **A score of 50 represents a neutral impact.** Scores above 50 indicate more positive performance, and scores below reflect more negative performance. A score of NA means not enough data is available on the company to generate a score.

The algorithms are sensitive to both **intensity** and **frequency**. Truvalue Labs data contribute an indication of how stakeholder issues and potential controversies may affect a company, based on real-time information. Truvalue assesses positive and negative ESG events contained in unstructured data and assigns a score per topic for each passage based on the magnitude of sentiment. The score reflects not only whether performance is positive or negative, but also how positively or negatively the company is performing on the topic reflected in the datapoint. For example, the algorithms would assign a relatively more negative score to a catastrophic oil spill affecting multiple workers and communities than to a workplace incident that caused a minor injury to one worker. In both cases, the sentiment-based score would be negative, but performance would be evaluated as significantly more negative in the first case than in the second case.

Cowen introduced its own ESG scoring methodology because we believe that existing ratings systems are mostly backward-looking. Data are often supplied by companies and thus are subject to "greenwashing" (i.e., using data selectively to spin a story that is better than it actually is). In addition, most ratings systems generally don't align with SASB, which we think is emerging as a standard on the buy side.

Dynamic Materiality™ is Truvalue Labs' approach acknowledging that companies, industries, and sectors have unique materiality signatures that evolve over time, determined by factors such as shifts in business models, changing consumer preferences, emerging technologies, and new regulations. Dynamic Materiality™ is driven by how stakeholders respond to events, behaviors, and externalities experienced in relation to a company or an industry. This stands in contrast to the view that materiality is relatively static and can be defined by a company. For example, if a company appeared in 100 different sources over a trailing 12-month period, and 30 of the sources were related to the SASB Employee Health & Safety category, the Employee Health & Safety Dynamic Materiality™ would be 30%. Furthermore, 30% of the company's overall score would be driven by the Employee Health and Safety Insight Score.

ESG MATERIALITY

Establishing **materiality** is critical to evaluating a company's ESG performance. Factors most material in one sector (or to a particular company) may not be as important to another. In addition, the factors that are material – and the degree to which factors are material – can change over time.

Applying data to frameworks established by SASB (the Sustainability Accounting Standards Board) and by Truvalue Labs, we present in the chart above the three most material ESG factors that investors should focus on for the company that is the subject of this report; the Dynamic Materiality™ of each factor (i.e., what percentage of overall materiality the category represents for the subject company); and a Score for the subject company in each of these three categories (on a 0 to 100 basis, with 50 being average).

We also calculate an **overall ESG Score** for the subject company, which is presented above (in green) and on the cover of this report. A full explanation of how this ESG Score is derived is presented below.

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The recommendation contained in this report was produced at July 25, 2022, 20:36 ET, and disseminated at July 26, 2022, 05:28 ET.

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Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

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Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield



Cowen and Company Equity Research Rating Distribution

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Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	715	72.88%	193	26.99%
Hold (b)	261	26.61%	18	6.90%
Sell (c)	5	0.51%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's equity research rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's equity research ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's equity research ratings definitions. Cowen and Company Equity Research Rating Distribution Table does not include any company for which the equity research rating is currently suspended or any debt security followed by Cowen Credit Research and Trading.

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Avantor Rating History as of 07/22/2022



Danaher Corporation Rating History as of 07/22/2022



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Invitae Corp Rating History as of 07/22/2022



Initiated Coverage - 03/09/2015 - Rating Outperform

Thermo Fisher Scientific Rating History as of 07/22/2022



Initiated Coverage - 2/2/2009 - Outperform Rating

Legend for Price Chart:

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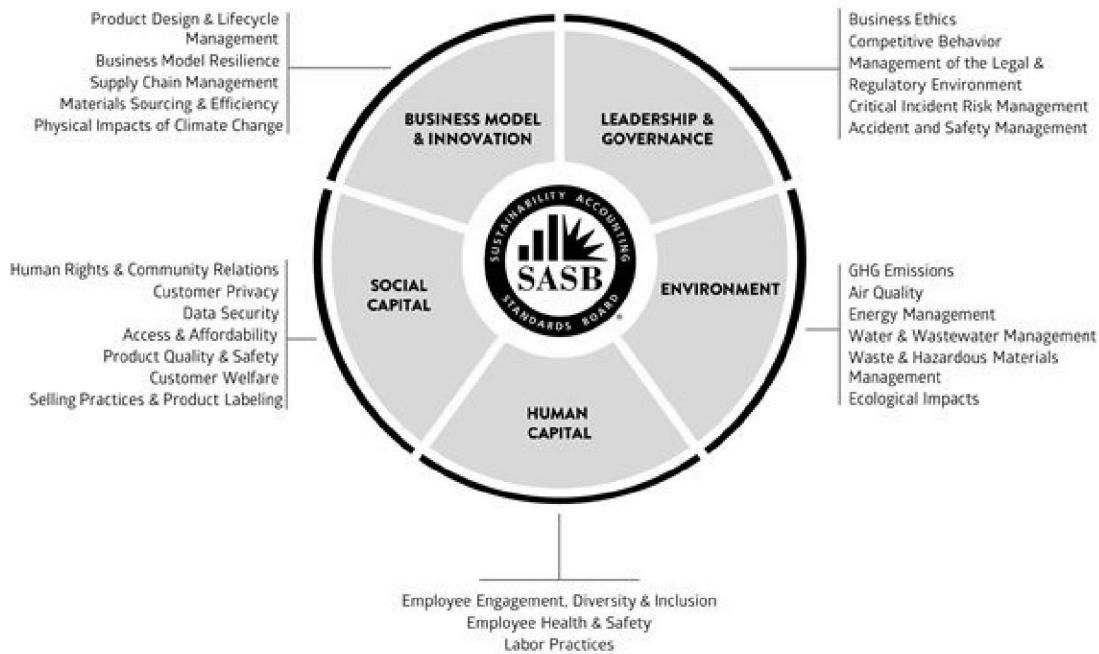
Invitae Corp
July 26, 2022

COWEN ESG SCORES

HOW ARE COWEN'S ESG SCORES CALCULATED?

Cowen leverages technology from Truvalue Labs to generate our ESG scores. Truvalue Labs uses artificial intelligence to capture the stakeholder view of how companies are performing on ESG metrics, using the Sustainability Accounting Standards Board (SASB) materiality framework (www.sasb.org). (See below.) These data are leveraged to calculate a score for each company, which allows Cowen to have a **common framework** and uniform way to approach ESG discussions with our clients. Cowen ESG scores appear on Company and Company Quick Take notes and are updated daily.

UNIVERSE OF 26 SUSTAINABILITY ISSUES ACROSS 5 AREAS



HOW DOES THE PROCESS WORK?

The process begins with capturing unstructured data from more than 100,000 sources, in 14 languages. These data are culled from a wide range of sources with varied perspectives, including industry publications, news outlets, NGOs, trade unions, government sources, legal and regulatory filings, and academic publications.

Natural language processing is used to interpret semantic content from the original sources and generate analytics by applying criteria consistent with established sustainability and ESG frameworks. Performance is scored on a 0 to 100 scale. **A score of 50 represents a neutral impact.** Scores above 50 indicate more positive performance, and scores below reflect more negative performance. A score of NA means not enough data is available on the company to generate a score.

The algorithms are sensitive to both **Intensity** and **frequency**. Truvalue Labs data contribute an indication of how stakeholder issues and potential controversies may affect a company, based on real-time information. Truvalue assesses positive and negative ESG events contained in unstructured data and assigns a score per topic for each passage based on the magnitude of sentiment. The score reflects not only whether performance is positive or negative, but also how positively or negatively the company is performing on the topic reflected in the datapoint. For example, the algorithms would assign a relatively more negative score to a catastrophic oil spill affecting multiple workers and communities than to a workplace incident that caused a minor injury to one worker. In both cases, the sentiment-based score would be negative, but performance would be evaluated as significantly more negative in the first case than in the second case.

WHY DO WE BELIEVE THAT OUR APPROACH IS BETTER THAN OTHERS?

Cowen introduced its own ESG scoring methodology because we believe that existing ratings systems are mostly backward-looking. Data are often supplied by companies and thus are subject to "greenwashing" (i.e., using data selectively to spin a story that is better than it actually is). In addition, most ratings systems generally don't align with SASB, which we think is emerging as a standard on the buy side.

DYNAMIC MATERIALITY™

Dynamic Materiality™ is Truvalue Labs' approach acknowledging that companies, industries, and sectors have unique materiality signatures that evolve over time, determined by factors such as shifts in business models, changing consumer preferences, emerging technologies, and new regulations. Dynamic Materiality™ is driven by how stakeholders respond to events, behaviors, and externalities experienced in relation to a company or an industry. This stands in contrast to the view that materiality is relatively static and can be defined by a company. For example, if a company appeared in 100 different sources over a trailing 12-month period, and 30 of the sources were related to the SASB Employee Health & Safety category, the Employee Health & Safety Dynamic Materiality™ would be 30%. Furthermore, 30% of the company's overall score would be driven by the Employee Health and Safety Insight Score.

COWEN
EQUITY RESEARCH

Invitae Corp
July 26, 2022



Invitae Corp (NVT) ESG Score History as of 07/26/2022



ESG performance is scored on a 0 to 100 scale. A score of 50 represents a neutral impact. Scores above 50 indicate more positive performance, and scores below reflect more negative performance. A blank chart means the company has an ESG performance score of N/A. A score of N/A means not enough data is available on the company to generate a score.
Source: Truvalue Labs

COWEN
EQUITY RESEARCH

Invitae Corp
July 26, 2022

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EXHIBIT 52



Wesco Aircraft
Liability Management

Witness Testimony Concludes on Day 30 of Incora/Wesco Trial

Fri 06/07/2024 09:34 AM EDT

Witness testimony concluded on day 30 of the Incora/Wesco [uptier exchange](#) trial yesterday, June 6. The trial will resume for closing arguments on June 24.

The last witness was Boris Steffen, managing director at Province, who testified for the UCC as an expert witness on mergers, acquisitions and restructurings. UCC counsel Theresa Foudy of Morrison Foerster called Steffen to counter the analysis of the March 2022 uptier transaction by Mark Rule, the managing director at AlixPartners, who [testified](#) on Wednesday.

Steffen disagreed with many aspects of Rule's analyses, including the conclusion that the transaction extended all debt maturities to 2026. He asserted that Rule had "ignored" the effect of springing maturities. The witness also disagreed that the \$770 million in new money referenced in Rule's report could be viewed as a benefit of the transaction, explaining that Incora/Wesco's ability to borrow under that basket would depend on market risk and company-specific risk.

Steffen also disagreed with Rule's evaluation of the impact of the transaction on Incora/Wesco's liquidity, highlighting once again the exclusion of springing maturities from Rule's analysis and noting there was a high degree of uncertainty on whether the company could raise new money. The witness also said that PIKing interest was not a benefit to the company because the "amount deferred simply accrues to the balance of debt."

Judge Isgur interjected to ask Steffen if accrual of interest is "just an argument never to borrow money." The witness said he believes there is a "short-term cash flow benefit" but also an increase in long-term debt. The judge asked if Steffen agreed that the transaction provided Incora/Wesco with "substantial" cash flow benefits in 2022, 2023 and early 2024. The witness agreed.

On cross-examination, counsel for Platinum pressed Steffen on whether he believed the reasonably equivalent value analysis should focus on the debtor's perspective. Steffen said it should. He also affirmed that Incora/Wesco owed its lenders the principal amount of debt at maturity, which could not be substituted by the fair market value at maturity. However, Steffen said he did substitute fair market value for principal value in his analysis.

When asked if he counted material liquidity benefits to Incora/Wesco as a positive outcome of the transaction when conducting his reasonably equivalent value analysis, Steffen responded he "just addressed Mr. Rule's" analysis. Counsel questioned Steffen again as to whether he included the increased liquidity benefits in his consideration of overall benefits of the transaction. The witness said, "I believe I considered them" and "I believe they were a benefit."

Judge Isgur said he was coming to a conclusion regarding the valuation of Incora/Wesco debt pre- and post-transaction. He noted that the witness demonstrated that the sum of all debt against the debtor was trading at a substantial discount prior to the transaction, which could be explained by insolvency or concerns about survivability. Judge Isgur asserted that after the transaction, when the sum of all debt began to trade for more, the "market must have reasoned that the transaction produced benefits." He asked, "What else would explain that increase in the sum of all debt trades?" Steffen responded that he was "not aware" of any other factors.

On redirect, Foudy followed up on Judge Isgur's inquiries about debt valuation. She asked Steffen if he analyzed all of the company's debt prior to the transaction, to which he responded no. The witness clarified that he did not look at the fair market value of the nonparticipating notes and agreed that he did not come to a conclusion about the fair market value of

all Incora/Wesco debt before and after the March 2022 transaction.

At the conclusion of the hearing, Judge Isgur admitted into evidence documents provided by the Incora debtors relating to the transmission of the [certification](#) of the additional 2026 notes by John McNichol of WSFS, the company's indenture trustee, the [validity](#) of which is disputed by the plaintiff parties.

Reorg's coverage of day one of the trial is [HERE](#), day two [HERE](#), day three [HERE](#), day four [HERE](#), day five [HERE](#), day six [HERE](#), day seven [HERE](#), day eight [HERE](#), day nine [HERE](#), day 10 [HERE](#), day 11 [HERE](#), day 12 [HERE](#), day 13 [HERE](#), day 14 [HERE](#), day 15 [HERE](#), day 16 [HERE](#), day 17 [HERE](#), day 18 [HERE](#), day 19 [HERE](#), day 20 [HERE](#), day 21 [HERE](#), day 22 [HERE](#), day 24 [HERE](#), day 25 [HERE](#), day 26 [HERE](#), day 27 [HERE](#), day 28 [HERE](#) and day 29 [HERE](#).

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EXHIBIT 53

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

U.S. BANK TRUST COMPANY, NATIONAL
ASSOCIATION, solely in its capacities as Trustees,

Plaintiffs,

v.

DISH DBS CORPORATION, DISH NETWORK L.L.C.,
ECHOSTAR INTERCOMPANY RECEIVABLE
COMPANY, L.L.C., DISH DBS ISSUER, LLC, and
DBS INTERCOMPANY RECEIVABLE COMPANY L.L.C.,

Defendants.

No. 1:24-cv-3646 (JGLC)

**ORAL ARGUMENT
REQUESTED**

**MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS**

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Defendants DISH DBS Corporation (“DBS”), DISH Network L.L.C. (“Network LLC”), EchoStar Intercompany Receivable Company, L.L.C. (“SATS Receivable”), DISH DBS Issuer, LLC (“DBS Issuer”), and DBS Intercompany Receivable Company L.L.C. (“DBS Receivable” and, collectively, “Defendants”), hereby submit this Memorandum of Law in support of their motion to dismiss the complaint (the “Complaint”)¹ filed by Plaintiffs U.S. Bank Trust Company (the “Trustees” or “Plaintiffs”), pursuant to Federal Rule of Civil Procedure 12(b)(6).

PRELIMINARY STATEMENT

EchoStar Corporation (“EchoStar”), through its subsidiaries, is a premier global provider of secure satellite communication solutions. DISH Network Corporation (“DISH”), through its subsidiaries, is a leading provider of television and retail wireless services, operating under the “DISH,” “Boost Mobile,” and “Sling TV” brands, among others. DBS, through its subsidiaries, owns and operates the pay-tv business of DISH. On December 31, 2023, EchoStar acquired DISH and its subsidiaries (the “Merger”), including Defendants here.

Shortly after the Merger, the newly-combined companies focused on the process of integrating the EchoStar and DISH business in a manner that facilitates synergies, cost saving, growth opportunities and achieves other anticipated benefits. In connection with such integration, they announced a series of transactions designed to unlock incremental strategic, financial, and operating flexibility for the combined business, including: (i) a transfer of certain wireless spectrum licenses from non-party DISH to a subsidiary of EchoStar (the “DISH Network Spectrum Transfer”); (ii) an assignment of approximately three million pay-tv subscribers from Defendant DBS to a wholly-owned DBS subsidiary, DBS Issuer (the “Subscriber Assignment”); (iii) an

¹ The Complaint was originally filed in the Supreme Court of the State of New York, New York County, index number 652184/2024. On May 14, 2024, the Complaint was removed to this Court pursuant to 28 U.S.C. §§ 1332(a), 1441, and 1446. (ECF No. 3) A true and correct copy of the Complaint is attached as **Exhibit A** to the Affirmation of Joshua D. Weedman, dated June 27, 2024, and attached hereto (the “Weedman Aff.”).

assignment of a portion of an intercompany loan between DBS and DISH to a non-party subsidiary of EchoStar (the “Intercompany Loan Transaction”); and (iv) the designation of various DBS subsidiaries as unrestricted subsidiaries (the “Sling TV Designation”) (together, the “Transactions”). (See Compl. ¶¶ 26, 44)

The Trustees sue purportedly at the direction of a group of dissident bondholders (the “Bondholders”) of DBS.² The claims here are without merit. *First*, Plaintiffs seek a declaration that two of the Transactions—the Subscriber Assignment and the Sling TV Designation—breached Section 4.07 of the Indentures. That section prohibits certain transactions unless DBS has sufficient “Restricted Payments” capacity under the Indentures to fund them, and DBS’s indebtedness to cash-flow ratio is no more than 8-to-1 after giving effect to such transactions (the “Leverage Ratio”). Plaintiffs’ claim is based on pure speculation that the Leverage Ratio exceeded 8-to-1 following the Transactions. But Plaintiffs acknowledge that an Officer’s Certificate was delivered to the Trustee weeks before the filing of this Complaint showing unambiguously that the Leverage Ratio following the Transactions was only 6.56-to-1. Plaintiffs’ “upon information and belief” allegations cannot be credited on a dismissal motion, especially because they are contradicted by documents referenced in the Complaint.

Second, Plaintiffs seek a declaration that DBS breached Section 5.01 of the Indentures, a

² At most, these Bondholders represent 38% of holders of the outstanding debt of DBS, and likely far less. The Bondholders hold only two of six DBS senior notes with near-identical indentures: (i) \$2 billion in 7.75% senior unsecured notes issued by DBS on June 13, 2016, with a maturity date of July 1, 2026 (the “2026 DBS Unsecured Notes”), (Compl. ¶ 28), and (ii) \$2.5 billion in 5.75% senior secured notes issued by DBS on November 26, 2021, with a maturity date of December 1, 2028 (the “2028 DBS Secured Notes” and, together with the 2026 DBS Unsecured Notes, the “DBS Bonds”). Both the 2026 DBS Unsecured Notes and the 2028 DBS Secured Notes were issued pursuant to the terms of an indenture (the “7.75% Indenture” and “5.75% Indenture,” respectively), which are identical in all material respects (together, the “Indentures”). (*Id.* ¶ 30) True and correct copies of relevant excerpts of the 7.75% Indenture and 5.75% Indenture are attached to the Weedman Affirmation as **Exhibits B** and **C**, respectively. Plaintiffs refer to, and selectively quote from, the Indentures throughout the Complaint, and these documents are therefore incorporated by reference. *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002). The holders of the remaining senior notes issued by DBS are not plaintiffs in this proceeding, despite the indentures with respect to these bonds being identical in all material respects to the Indentures governing the DBS Bonds.

boilerplate successor obligor provision, because the Intercompany Loan Transaction allegedly involved a transfer by DBS of “all or substantially all” of its assets. Under established law, the Intercompany Loan Transaction did not involve anything close to “all or substantially all” of DBS’s assets. In fact, the Intercompany Loan Transaction involved an assignment of a \$4.7 billion portion (the “Tranche A Portion”) of the \$7.4 billion Intercompany Loan from DBS to its affiliate, at a time when DBS had assets of approximately \$21 billion. Furthermore, the Tranche A Portion contributed no revenue to DBS’s business, which generated over \$11 billion annually in 2023. Thus, the assignment involved only 22% of DBS’s asset base and 0% of its revenue base, which is nowhere close to “all or substantially all” of DBS’s assets.

Third, Plaintiffs argue that the Transactions constitute fraudulent transfers under the Colorado Uniform Fraudulent Transfer Act (“CUFTA”). Plaintiffs have failed to plead their CUFTA claims with particularity, and instead try to insinuate that routine corporate transactions are fraudulent simply because they are part of some undefined “scheme,” which is insufficient under Rule 9(b). The Complaint contains little more than conclusory recitations of the statutory elements of fraudulent transfer claims and conclusory allegations made on “information and belief,” neither of which is sufficient under Rule 9 or otherwise. Moreover, the Transactions are not “transfers” under CUFTA because there has been no disposition of any assets to a third party. Internal reorganizations are not fraudulent transfers. None of the assets at issue here, other than a portion of the Intercompany Loan, have been transferred away from the issuer, DBS.

The Complaint should be dismissed.

BACKGROUND³

A. The Parties

Non-party EchoStar is a Colorado-based satellite broadband platform. (Compl. ¶ 17) Non-party DISH is a leading provider of television and retail wireless services, and a wholly-owned, direct subsidiary of EchoStar. (*Id.* ¶¶ 19, 41) Defendant DBS is an indirect subsidiary of both DISH and EchoStar and is a holding company of its subsidiaries, which offer cable and streaming television services under the “DISH” and “Sling TV” brands. (*Id.*) The remaining Defendants include: (i) Network LLC, a wholly-owned subsidiary of DBS, (ii) DBS Issuer, a wholly-owned subsidiary of Network LLC, (iii) DBS Receivable, a wholly-owned subsidiary of Network LLC, and (iv) SATS Receivable, a wholly-owned subsidiary of non-party EchoStar. (*Id.* ¶¶ 12–16)⁴

Plaintiff U.S. Bank, as Trustee, is a national banking association and designated trustee under the terms of the Indentures. (*Id.* ¶ 11) The Complaint alleges that the Trustee is acting at the direction of a “majorit[y] of the holders” of the DBS Bonds to bring these claims pursuant to the Indentures. (*Id.*) The Complaint does not disclose the holders of the DBS Bonds or the total aggregate amounts allegedly held by them. The Trustee brought this case on behalf of “all the holders,” even though the majority of these bondholders opted to not join in this suit. (*Id.*)⁵

B. The DBS Notes And Indentures

On June 13, 2016, DBS issued the 2026 DBS Unsecured Notes, maturing July 1, 2026.

³ The facts below are drawn from the allegations in the Complaint, documents cited therein and integral to it, and those incorporated by reference. *Chambers*, 282 F.3d at 153; *see also L-7 Designs, Inc. v. Old Navy, LLC*, 647 F.3d 419, 422 (2d Cir. 2011) (courts may consider documents integral to complaint). The facts herein also draw from publicly filed documents, of which the Court may take judicial notice. *Rein v. Esper*, No. 16-cv-7359, 2018 WL 10561521, at *2 (S.D.N.Y. Feb. 27, 2018).

⁴ Several non-parties are also referenced in the Complaint, including: (i) non-party EchoStar Wireless Holding L.L.C. (“SATS Wireless”), a wholly-owned subsidiary of EchoStar; and (ii) non-parties Sling TV Holding L.L.C., Sling TV Purchasing L.L.C., Sling TV L.L.C., and Sling TV Gift Card Corporation (together, the “Sling TV Entities”), which are wholly-owned subsidiaries of Defendant DBS. (Compl. ¶¶ 18–23)

⁵ *See* note 2, *supra*.

(*Id.* ¶ 28) On November 26, 2021, DBS issued the 2028 DBS Secured Notes, maturing December 1, 2028. (*Id.* ¶ 30) The Indentures, which are identical in all material respects, are both governed by New York law. (*Id.* ¶ 32). Plaintiffs allege that the Transactions caused DBS to breach Sections 4.07 and 5.01 of the Indentures. (*Id.* ¶¶ 94–95, 99–100)

1. § 4.07—Restricted Payments And The “Builder Basket”

Section 4.07 limits DBS’s ability to make certain “Restricted Payments” to entities that are not obligated to act as guarantors under the DBS Notes, but allows DBS to make “Restricted Payments” where: (i) DBS is not in default under the Indentures at the time of the transfer, or the transfer would not result in an “Event of Default”; (ii) DBS’s indebtedness to cash-flow does not exceed the 8-to-1 Leverage Ratio; and (iii) the subject transfer, together with any prior “Restricted Payments,” is not more than a calculated capacity, colloquially referred as a “builder basket.” (Ex. B at 46–47; Ex. C at 47–49; *see also* Compl. ¶ 96)

The 8-to-1 Leverage Ratio is measured at the time of the transaction in question, and is calculated by comparing DBS’s “Consolidated Cash Flow” to its indebtedness over the prior fiscal year after giving effect to the subject “Restricted Payments.” (*Id.* ¶¶ 88–89) The “builder basket” capacity accumulates over time based on DBS’s cash flows, and it is calculated under Section 4.07(e)(iii). (Compl. ¶ 87) The calculation includes accumulations starting January 1, 2002, covering capacity growth over more than twenty years of consolidated cash flows. (Exs. B, C at §4.07(e)(iii)(A)(y)) DBS had over \$28 billion of capacity under its “builder basket” to use for “Restricted Payments” at the time of the Transactions. (Compl. ¶ 93; *see also* § I(A), *infra*)

2. § 5.01—Successor Obligor Provision And “All Or Substantially All”

Pursuant to Section 5.01 of the Indentures, DBS is permitted to effectuate certain transactions that do not result in the transfer, sale, assignment, or disposal of “all or substantially all” of DBS’s assets:

The Company shall not ... sell, assign, transfer, lease, convey or otherwise dispose of all or substantially all of its properties or assets in one or more related transactions to, another Person

(Ex. B at 69–70; Ex. C at 71–72; *see also* Compl. ¶ 96) At the time of the Transactions, DBS’s consolidated asset base was approximately \$21 billion, a figure publicly disclosed in DBS’s SEC filings,⁶ including: (i) eight million pay-tv subscribers; (ii) the Intercompany Loan; and (iii) certain spectrum licenses, real estate, and orbital satellites. (*See* Ex. D at 31–32, F4–F5)

C. The EchoStar/DISH Merger

On August 8, 2023, DBS’s current parent companies, non-parties EchoStar and DISH, announced an agreement to merge. (*Id.* ¶ 40) Initially, the plan entailed DISH acquiring EchoStar, but on October 2, 2023, the companies announced that the proposed structure of the deal would be amended, with EchoStar acquiring DISH and its various affiliates as part of an all-stock deal. (*Id.* ¶ 41)⁷ The Merger closed on December 31, 2023. (*Id.* ¶ 41)

D. DBS Seeks To Improve Its Capital Structure

Shortly after the Merger, EchoStar announced the Transactions, a series of intercompany reorganizations whereby certain assets were assigned or transferred to other subsidiaries within the broader EchoStar structure. (*Id.* ¶ 44) The Transactions included:

- ***The DISH Network Spectrum Transfer***—non-party DISH transferred certain of its wireless spectrum licenses to a subsidiary of EchoStar, non-party SATS Wireless. (*Id.*) The DBS Bonds, held by the purported Bondholders here, are not secured by DISH’s assets or the subject wireless spectrum licenses, and Plaintiffs bring no claims on account of the DISH Network Spectrum Transfer, despite referring to it throughout the Complaint as an alleged “harm” and “deeply prejudicial.” (*See, e.g., id.* ¶¶ 9, 42, 70, 85)
- ***The Subscriber Assignment***—DBS assigned approximately 3 million pay-tv subscribers

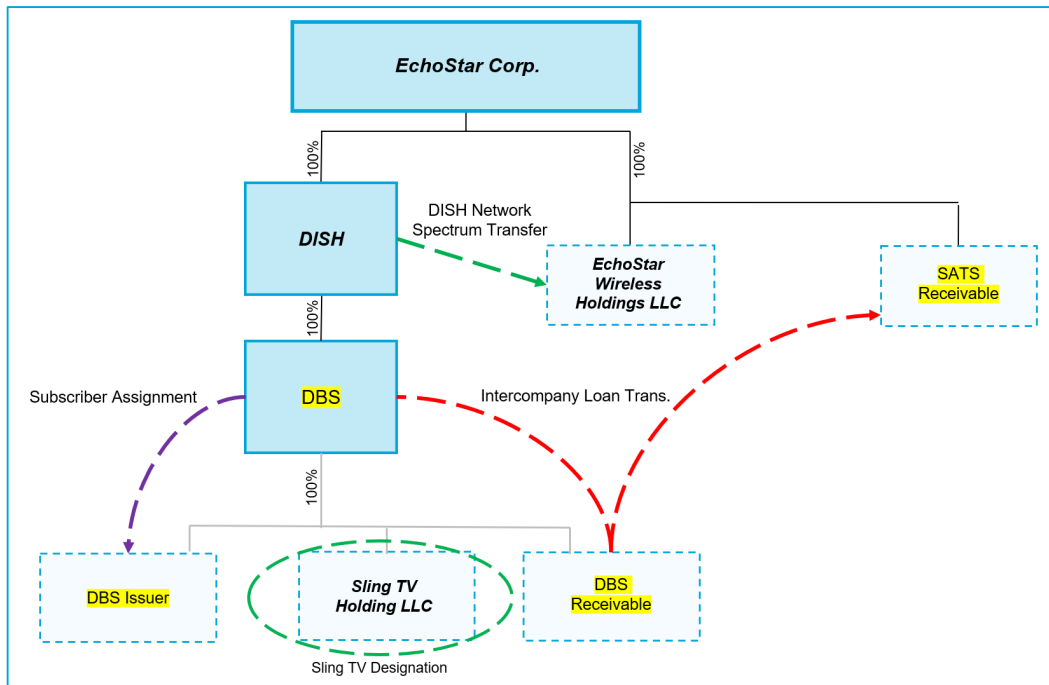
⁶ *See, e.g.,* DISH DBS Corporation, Form 10-K (Apr. 1, 2024) (the “2023 DBS 10-K”) at 31–32, F4–F5. A true and correct copy of excerpts of the 2023 DBS 10-K is attached to the Weedman Affirmation as **Exhibit D**; *see also Rothman v. Gregor*, 220 F.3d 81, 88 (2d Cir. 2000) (court can take judicial notice of documents filed with the SEC).

⁷ Plaintiffs insinuate there was something nefarious about the fact that the merger was changed so that EchoStar acquired DISH instead of the other way around, but SEC filings explained very clearly the rationale for the revised merger. *See* EchoStar Corporation, Form S-4 (Oct. 3, 2023) at 54–55 (the “Form S-4”). A true and correct copy of an excerpt of the Form S-4 is attached to the Weedman Affirmation as **Exhibit E**; *see also Rothman*, 220 F.3d at 88.

to its wholly-owned subsidiary DBS Issuer, and designated it as unrestricted subsidiary. (*Id.* ¶ 44) The fair market value of the assigned subscribers at the time was approximately \$5.4 billion and comprised approximately 46% of DBS’s overall subscriber base, (*see id.* ¶¶ 26, 44, 80), or approximately 26% of DBS’s total asset base. The income derived from the 3 million pay-tv subscribers, approximately \$4.5 billion annually, continues to flow up to DBS vis-à-vis Network LLC, a wholly-owned subsidiary of DBS.

- **The Intercompany Loan**—DBS transferred to SATS Receivable the Tranche A Portion of the approximately \$7.4 billion Intercompany Loan from DBS to DISH, by way of an assignment from DBS Receivable. (*Id.* ¶ 44) The fair-market value of the Tranche A portion was approximately \$4.7 billion, approximately 22% of DBS’s total asset base.
- **The Sling TV Designation**—DBS designated various subsidiaries of its affiliate, Sling TV, L.L.C., as unrestricted. *Id.* As set forth in the Complaint, the Sling TV Designation is only relevant to the alleged breach of Section 4.07 of the Indentures. (*Id.* ¶ 112)

Giving effect to the Transactions, a simplified organizational structure of EchoStar is as follows⁸:



E. The Proposed Exchange Offers

In January 2024, EchoStar launched two exchange offers directed at certain classes of pre-Merger notes issued by non-party DISH and Defendant DBS. (*Id.* ¶¶ 45, 55) On January 12, 2024, EchoStar announced a proposal to exchange certain classes of bonds issued by non-party DISH

⁸ Entities in yellow are the Defendants; entities depicted by italicized, bolded font are non-parties to this suit.

for new secured bonds issued by EchoStar (the “DISH Exchange Offer”) (*id.* ¶ 45), which expired on February 12, 2024, after the minimum amount of tendering holders was not met (*id.* ¶ 54).

On January 16, 2024, EchoStar announced an additional exchange offer, whereby DBS Issuer would issue secured bonds in exchange for four series of unsecured notes previously issued by DBS (the “DBS Exchange Offer”). (*Id.* ¶ 56) The DBS Exchange Offer provided all holders of the applicable DBS bonds the opportunity to participate in the exchange. On January 29, 2024, EchoStar elected to terminate the DBS Exchange Offer. (*Id.* ¶ 60)

F. DBS’s April 2024 Officer’s Certificate

On March 26, 2024, the Trustees sent DBS three identical notices, pursuant to Section 4.07 of the Indentures, requesting a certified statement of all permissible “Restricted Payments” made in the preceding six months (the “Trustees’ Notices”). On April 9, 2024, DBS sent the Trustees a certified statement with detailed calculations of DBS’s compliance with the 8-to-1 Leverage Ratio requirement and “builder basket” capacity under Section 4.07 (the “Officer’s Certificate”).⁹ (Ex. G at 6 (showing a 6.56-to-1 Leverage Ratio and remaining “builder basket” capacity of \$18.1 billion))

LEGAL STANDARD

To survive a motion to dismiss, a complaint must “allege[] facts sufficient ‘to state a claim to relief that is plausible on its face.’” *Seren Fashion Art and Interiors, LLC v. B.S.D. Capital, Inc.*, 23-cv-2349, 2023 WL 7529768, at *3 (S.D.N.Y. Nov. 13, 2023) (Clarke, J.). “Conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to defeat a motion to dismiss.” *Kirch v. Liberty Media Corp.*, 449 F.3d 388, 398 (2d Cir. 2006). A court will consider documents incorporated by reference or integral to the complaint. *WW Servs., Ltd. v.*

⁹ True and correct copies of the Trustees’ Notices and the Officer’s Certificate are attached to the Weedman Affirmation as **Exhibits F** and **G**, respectively; *see also Rothman*, 220 F.3d at 88.

Bombardier Aerospace Corp., 14-cv-7343, 2015 WL 5671724, at *8 (S.D.N.Y. Sept. 22, 2015); *L-7 Designs*, 647 F.3d at 422 (“A complaint is also deemed to include any ... documents that, although not incorporated by reference, are ‘integral’ to the complaint.”). Although a court ordinarily “accept[s] as true all factual allegations in the complaint,” “that tenet does not extend to ‘factual assertions that are contradicted by the complaint itself, by documents upon which the pleadings rely, or by facts of which the court may take judicial notice.’” *NRW, Inc. v. Bindra*, 12-cv-8555, 2014 WL 4449779, at *4 (S.D.N.Y. Sept. 10, 2014); *see also Ahearn v. Brachowicz*, 13-cv-8007, 2014 WL 3408389, at *3 (S.D.N.Y. July 10, 2014) (allegations contradicted by more specific allegations or documentary evidence “not entitled to a presumption of truthfulness”).

ARGUMENT

I. THE COMPLAINT FAILS TO STATE A CLAIM FOR BREACH

“Interpretation of indenture provisions is a matter of basic contract law.” *Sharon Steel Corp. v. Chase Manhattan Bank, N.A.*, 691 F.2d 1039, 1049 (2d Cir. 1982). A complaint alleging breach of an indenture must sufficiently demonstrate how the debtor failed to perform its obligations under the express covenants set forth in the agreement. *Metro. Life Ins. Co. v. RJR Nabisco, Inc.*, 716 F. Supp. 1504, 1518 (S.D.N.Y. 1989). Plaintiffs’ claims for breaches of Sections 4.07 and 5.01 of the Indentures are patently deficient.

A. Plaintiffs Fail To Sufficiently Plead Breach Of § 4.07

Section 4.07 allows DBS to effectuate certain “Restricted Payments.” Provided that DBS maintains compliance with an 8-to-1 indebtedness to cash-flow ratio, after giving effect to the transaction in question, it can access the “builder basket” for payments or transactions that would otherwise constitute a prohibited “Restricted Payment” under the terms of the Indentures. (*Id.* ¶¶ 87–88)

Plaintiffs offer only a conclusory assertion that, “on information and belief,” DBS did not

satisfy the 8-to-1 Leverage Ratio after effectuating the Transactions. (*Id.* ¶¶ 94, 118) But unsubstantiated, conclusory statements, premised only on “information and belief,” are insufficient to sustain a claim for breach. *See, e.g., Citizens United v. Schneiderman*, 882 F.3d 374, 384 (2d Cir. 2018) (“A litigant cannot merely plop upon ‘information and belief’ in front of a conclusory allegation and thereby render it non-conclusory.”); *HSM Holdings, LLC v. Mantu I.M. Mobile Ltd.*, 20-cv-00967, 2021 WL 918556, at *16 n.4 (S.D.N.Y. Mar. 10, 2021) (“Courts in this Circuit look unfavorably upon conclusory pleadings made on information and belief.”); *Taboola, Inc. v. Ezoic Inc.*, 17-civ-9909, 2020 WL 1900496, at *10 (S.D.N.Y. Apr. 17, 2020) (“It is not enough for [a plaintiff] to baldly state [] ‘upon information and belief’” without “a concrete factual foundation for such assertions”).

Further, Plaintiffs’ allegations are refuted by a document referenced in the Complaint: the Officer’s Certificate, which calculates DBS’s indebtedness to cash-flow ratio at 6.56-to-1 following the Transactions. (*See* Ex. G at 6) Thus, DBS did not exceed the 8-to-1 Leverage Ratio.

The Complaint does not offer any other calculation of the Leverage Ratio or identify any mistakes. In fact, the Complaint essentially concedes that Plaintiffs have no basis to challenge the calculations set forth in the Officer’s Certificate, admitting in a footnote that the Trustees’ claim under Section 4.07 is made at the direction of the Bondholders, reserving the right to rely on the determination of this Court as to whether a breach has in fact occurred. (Compl. ¶ 94 n.27)

B. Plaintiffs Fails Sufficiently To Plead Breach Of § 5.01

Section 5.01 of the Indentures provides that “[DBS] shall not consolidate or merge with or into...or sell, assign, transfer, lease, convey or otherwise dispose of all or substantially all of its properties or assets,” subject to certain exceptions set forth in the provision. (Exs. B, C, § 5.01; Compl. ¶ 96) Plaintiffs allege, again “on information and belief,” that DBS’s only asset was the approximately \$7.4 billion Intercompany Loan with non-party DISH, and that a portion of the

Intercompany Loan disposed of “all or substantially all” of DBS’s assets.¹⁰ (Compl. ¶¶ 98, 99) Plaintiffs’ allegation is demonstrably incorrect. DBS transferred only 22% of its assets, which is not nearly “all or substantially all.”

1. Successor Obligor Clauses Do Not Apply To Corporate Reorganizations

Successor obligor provisions such as Section 5.01 do not apply to internal reorganizations. “Successor obligor provisions have two purposes: to leave the borrower free to merge, liquidate or to sell its assets in order to enter a wholly new business free of public debt and to assure the lender ‘a degree of continuity of assets.’” *Bank of N.Y. v. Tyco Int’l Group, S.A.*, 545 F. Supp. 2d 312, 322 (S.D.N.Y. 2008). Because a creditor’s interest is in a company’s continued operations, corporate restructurings of the type effectuated here are routinely found not to trigger a successor obligation. *Id.* at 321 (“[The subject company] was restructured, not liquidated ... [and] [t]here is no indication that successor obligor clauses were intended to require consent from the noteholders for such internal restructuring, even when coupled with a spin-off of some of the obligor’s assets.”); *Resnick v. Karmax Camp Corp.*, 149 A.D.2d 709, 709 (2d Dept. 1989) (transfer of assets to newly formed subsidiaries not disposition of all or substantially all assets); *Gimbel v. Signal Co., Inc.*, 316 A.2d 599, 605 (Del. Ch. 1974) (“[I]t is not our law that [] approval is required upon every ‘major’ restructuring of the corporation.... The statute requires [] approval upon the sale of ‘all or substantially all’ of the corporation’s assets. That is the sole test to be applied.”).

Tyco is instructive. In *Tyco*, a trustee claimed a corporate spin-off would violate an indenture covenant (near identical to Section 5.01 here) stating that the transferor-company “will not...sell or convey all or substantially all of its assets to any Person,” subject to certain exceptions. 545 F. Supp. 2d at 314. The court looked at the substance of the transaction and noted that:

¹⁰ The Complaint makes no allegations under Section 5.01 with regard to any of the other three Transactions, *i.e.*, the Spectrum Transfer, the Subscriber Assignment, or the Sling TV Designation.

Before the Transaction, Tyco was a public corporation that maintained four lines of business through a single holding company, TIGSA.... After the Transaction, Tyco ... maintains two lines of business through a single holding company, TIFSA.... The noteholders remain lenders to Tyco, but Tyco divested itself of two lines of business. In essence, Tyco spun off two of its businesses.

Id. at 320. Mindful of the purpose of successor obligor clauses, the court concluded that the successor obligor clause was not implicated: “There is no indication that successor obligor clauses were intended to require consent from the noteholders for such internal restructuring, even when coupled with a spin-off of some of the obligor’s assets.” *Id.* at 320–21.

Here, there is continuity in the assets held by DBS. Prior to the Intercompany Loan Transaction, DBS was an indirect subsidiary of DISH that held approximately 8 million pay-tv subscribers, various other miscellaneous assets, and the Intercompany Loan. (Compl. ¶ 44) Today, DBS remains an indirect subsidiary of DISH that holds approximately 5 million pay-tv subscribers directly, which are valued at approximately \$7.5 billion, in addition to approximately \$1.9 billion in other assets, as well as the remaining portion of the Intercompany Loan, with a value of approximately \$2.7 billion. Together, these remaining assets total approximately \$12.1 billion. *See Tyco*, 545 F. Supp. 2d at 322 (“Assuming that [the transferred assets] did not represent substantially all of [the transferor’s] assets, the lenders have maintained the requisite degree of continuity of assets. The successor obligor clauses require nothing more.”).

2. Plaintiffs Fail to Plead The Intercompany Loan Transaction Breached § 5.01

Plaintiffs’ claim that the Intercompany Loan Transaction constitutes “all or substantially all” of DBS’s assets is without merit. Plaintiffs’ argument that DBS’s only asset with any meaningful value was the Intercompany Loan,¹¹ which had a fair-market value of approximately

¹¹ Plaintiffs acknowledge that DBS’s asset base includes the equity it holds in its various subsidiary entities. (Compl. ¶ 97) However, the Complaint alleges that this equity should not be considered when calculating DBS’s assets because

\$7.4 billion, is demonstrably false.¹² (*Id.* ¶¶ 97, 122)

“Determining whether a transaction constitutes a disposal of all or substantially all of an entity’s assets ‘requires an inquiry into both the quantitative and qualitative aspects’ of the transaction in question.” *Whitebox Relative Value Partners, LP v. Transocean Ltd.*, 20-cv-07143, 2020 U.S. Dist. Lexis 237497, at *11 (S.D.N.Y. Dec. 16, 2020); *In re BankAtlantic Bancorp, Inc. Litig.*, 39 A.3d 824, 838 (Del. Ch. Feb. 27, 2012) (applying New York law). Here, both qualitative and quantitative assessments demonstrate clearly that the Intercompany Loan Transaction did not involve the sale or disposition of assets held by DBS, much less all or substantially all of them.

a. Plaintiffs Fails To Plead Breach Under A Quantitative Analysis

Under the quantitative assessment, when considering the assets retained by the transferor, courts look to both book value and market value, as well as the income-producing nature of the assets at issue. *BankAtlantic*, 39 A.3d at 838. Here, the Tranche A portion of the Intercompany Loan represents \$4.7 billion of the Intercompany Loan, which had a total fair-market value of approximately \$7.4 billion, so only 63% of that single asset. (Compl. ¶ 44; *see also* Ex. D at F4) And as is relevant, the Tranche A Portion constitutes approximately 22% of DBS’s overall asset base, which falls well short of “all or substantially all” of DBS’s assets.¹³ *See, e.g., HFTP Invs. v. Grupo TMM, S.A.*, 2004 N.Y. Misc. Lexis 3248, at *10 (Sup. Ct. N.Y. Cnty. June 4, 2004) (75% of total assets quantitatively not substantially all assets”); *Sharon Steel*, 691 F.2d at 1051 (51% of book value not “even close” to satisfying “all or substantially all”); *Story v. Kennecott Copper*

it is encumbered by debt. (*Id.* ¶ 98) Plaintiffs do not cite to any law or economic principle, in this jurisdiction or elsewhere, that requires that such equity be disregarded in the manner that Plaintiffs propose.

¹² *See* Ex. D at F4–F5.

¹³ The Complaint misleadingly characterizes the Tranche A portion of the Intercompany Loan Transaction as being the entirety of the underlying loan itself (*see, e.g.,* Compl. ¶¶ 4, 39, 44, 65, 67, 77, 129), only acknowledging in passing that it was in fact part of a larger loan amount that totaled approximately \$7.4 billion, meaning that the Transaction itself only involved 63% of the asset’s overall value. (*Id.* ¶ 98, 122)

Corp., 90 Misc.2d 333, 335–36 (Sup. Ct. N.Y. Cnty. 1977) (55% of company’s assets not “all or substantially all”).

b. Plaintiffs Fails To Plead Breach Under A Qualitative Analysis

Under the qualitative analysis, courts consider “whether ‘the sale substantially changed the nature or character of the entity’s business,’ ... whether ‘the sale was one not in the normal and regular course of the entity’s business,’” *Transocean*, 2020 U.S. Dist. Lexis 237497, at *11, and “involved primarily the entity’s operating assets, rather than its liquid assets.” *HFTP*, 2004 N.Y. Misc. Lexis 3248, at *11; *see also Roseton OL, LLC v. Dynegy Holdings, Inc.*, 2011 Del. Ch. Lexis 113, at *52 (Del. Ch. July 29, 2011).

Here, there has been no change to DBS’s existence, purpose, or fundamental business. Prior to the Transactions, DBS was an indirect holding-company subsidiary of DISH that held approximately eight million pay-tv subscribers, various miscellaneous assets, and the Intercompany Loan. (Compl. ¶ 44) Today, DBS remains an indirect holding-company subsidiary of DISH that holds approximately five million DISH-TV subscribers, valued at approximately \$7.5 billion, in addition to approximately \$1.9 billion in other assets, as well as the remaining portion of the Intercompany Loan, valued at approximately \$2.7 billion. Together, these remaining assets total almost \$12.1 billion. Thus, DBS’s existence, purpose, and business are fundamentally the same. *See Transocean*, 2020 U.S. Dist. Lexis 23749, at *15 (internal reorganization not breach of successor obligor provision because it “posed no risk” to transferor’s ability to satisfy outstanding debt because assets were not transferred away from transferor’s ultimate ownership).

Plaintiffs try to avoid these inescapable conclusions by asserting that the Intercompany Loan was the “crown jewel” of DBS, (Compl. ¶ 98), which defies credulity. Indeed, it is hard to identify an asset less subject to the characterization of “crown jewel” than the Intercompany Loan, which is not an operating asset. No court has ever found an intercompany loan to be a “crown

jewel” of a company, and the suggestion that 22% of DBS’s overall asset base, outside of its primary line of business (*i.e.*, pay-tv subscribers), constitutes a “crown jewel” is patently implausible. *See, e.g., In re Adelpia Communs. Corp.*, No. 02-41729, 2015 U.S. Dist. Lexis 33229, at *30–31 (S.D.N.Y. Mar. 17, 2015) (selling small portion of debtor’s subscriber base not “crown jewel” asset); *cf. In re Tronox Inc.*, 503 B.R. 239, 252 (Bankr. S.D.N.Y. 2013) (profitable business line spun-off to isolate from creditors was debtor’s “crown jewel” in light of company’s liabilities); *ASARCO LLC v. Ams. Mining Corp.*, 396 B.R. 278 (S.D. Tex. 2008) (asset that generated almost all of debtor’s net income was “crown jewel”).

II. PLAINTIFFS FAIL TO PLEAD ANY FRAUDULENT TRANSFER

The Complaint alleges four counts of fraudulent transfer pursuant to Colorado’s Uniform Fraudulent Transfer Act (“CUFTA”).¹⁴ (*See generally* Compl. ¶¶ 125–54) These include an actual intentional and constructive fraudulent transfer claim for both the: (i) the Intercompany Loan Transaction; and (ii) the Subscriber Assignment.¹⁵ All four claims fail.

A. Plaintiffs Fail To Adequately Plead An Actual Fraudulent Transfer

To plead an actual fraudulent transfer claim, a complaint must allege facts sufficient to demonstrate that each of the subject transfers was made with the “actual intent to hinder, delay, or defraud [a] creditor.” C.R.S.A § 38-8-105(1)(a); *see also In re Blair*, 594 B.R. 712, 741 (Bankr. D. Colo. 2018) (“[A] cause of action for ‘actual intent to hinder, delay, or defraud’ commonly is referred to as a claim for ‘actual fraud.’”). Courts may also consider additional factors, referred to as the “badges of fraud,” to determine if there are sufficient grounds to infer fraudulent intent. §

¹⁴ Decisions from other jurisdictions that have adopted a version of the Uniform Fraudulent Transfer Act can serve as guidance when evaluating CUFTA claims. *CB Richard Ellis, Inc. v. CLGP, LLC*, 251 P.3d 523, 529 (Colo. App. 2010) (“[B]ecause CUFTA was derived from the Uniform Fraudulent Transfer Act (UFTA) ... we may consult cases decided under other states’ versions of UFTA for assistance.”).

¹⁵ Plaintiffs complain about all four Transactions throughout the Complaint, but only bring their fraudulent transfer claims on account of the Intercompany Loan Transaction and Subscriber Assignment. (Compl. ¶¶ 126, 133, 142, 148)

38-8-105(2); *see also Schempp v. Lucre Mgmt. Grp., LLC*, 75 P.3d 1157, 1165 (Colo. App. 2003) (“[T]he intent to hinder, delay, or defraud creditors must be established by the creditor, typically by showing a number of ‘badges of fraud.’”). Plaintiffs here fail on both fronts.

1. Plaintiffs Fail To Plead Actual Intent With Particularity

Actual fraudulent transfer claims are subject to the heightened pleading standards of Rule 9(b). *See* FED. R. CIV. P. 9(b); *In re Sharp Int’l Corp.*, 403 F.3d 43, 56 (2d Cir. 2005) (“As ‘actual intent to hinder, delay, or defraud’ constitutes fraud, it must be pled with specificity, as required by [Rule] 9(b).”); *see also Weinman v. McCloskey*, 14-cv-00296, 2015 U.S. Dist. Lexis 43018, at *30–31 (Colo. Dist. Ct. Mar. 31, 2015) (actual fraud claim under CUFTA subject to Rule 9(b)). Here, Plaintiffs complain about numerous routine corporate transactions, and then claim they add up to a broad “scheme” to defraud creditors. But simply arguing that routine corporate activities constitute a “scheme” to defraud, without explaining *how* they are fraudulent, does not satisfy Rule 9’s heightened pleading standard. *See, e.g., Smith v. N.Y. Pres. Hosp.*, 06-cv-4056, 2007 WL 2142312, at *5 (S.D.N.Y. July 18, 2007) (“Although [plaintiff] manages to sketch out the nature of that claim by generally stating the ‘who, what, where, when and how’ of his theory of fraud, he fails to provide sufficient detail about that theory or about any specific fraudulent claim.”). Even without Rule 9, the Complaint would fail to sufficiently plead an actual fraudulent transfer claim.

First, transactions carried out in the ordinary course of business create a rebuttable presumption against actual fraudulent transfer claims. *In re Sender*, 423 F. Supp. 2d 1155, 1170 (D. Colo. 2006) (ordinary course transactions create a rebuttable presumption against an actual fraud claim under CUFTA); *RTC Mortg. Tr. 1995-S/NI v. Sopher*, 171 F. Supp. 2d 192, 201 (S.D.N.Y. 2001) (New York analogue to CUFTA). Here, the Intercompany Loan Transaction and Subscriber Assignment were announced shortly after the Merger and carried out as part of a broader effort to integrate the newly-merged entities in a manner that, *inter alia*, helped strengthen

their balance sheets and improve their debt maturity profile, which are prudent and ordinary course transactions. *See Tyco*, 545 F. Supp. 2d at 321 (corporate restructuring involving transfer of assets between two holding companies was “made in the regular course of business”).

Second, the Subscriber Assignment—an intercompany assignment of three million pay-tv subscribers from one subsidiary to another within the EchoStar corporate structure—where the assignee subsidiary is itself a wholly-owned subsidiary of the assignor—is not a “transfer” under CUFTA, which is expressly defined as the “disposing of or parting with an asset or an interest in an asset,” neither of which have occurred here. § 38-8-102(13); *Sands v. New Age Fam. P’ship, Ltd.*, 897 P.2d 917, 919–20 (Colo. App. 1995) (“[The term] ‘transfer’ [under CUFTA] refers to property, assets, or money ... conveyed from the debtor to a third party” by way of a “transaction by which the debtor sought to place assets beyond the reach of creditors.”). The three million subscribers are now held by a wholly-owned subsidiary of DBS—Defendant DBS Issuer—and a DBS subsidiary, Network LLC, continues to receive the revenue from these subscribers. (*See* § I(B)(1)(b), *supra*) Thus, no asset has been “disposed of” or “conveyed to a third party.”

Third, there are no allegations that the Transactions have left DBS unable to pay its debts. Before the Transactions DBS had assets in excess of \$21 billion, and after the Transaction it has assets of approximately \$16.3 billion, and retains all the income and \$4.3 billion of value from the three million subscribers it assigned to its wholly-owned subsidiary. *See Dynegy*, 2011 Del. Ch. Lexis 113, at *65–66 (no transfer when transferor retained same value before and after subject transaction); *cf. Transocean*, 2020 U.S. Dist. Lexis 237497, at *12 (same).

2. Plaintiffs Fail To Plead The “Badges of Fraud”

In the absence of sufficient allegations of actual fraudulent intent, Plaintiffs must

demonstrate enumerated “badges of fraud.”¹⁶ *Blair*, 594 B.R. at 756. Plaintiffs must plead these “badges” with particularity. *In re Actrade Fin. Techs., Ltd.*, 337 B.R. 791, 809 (Bankr. S.D.N.Y. 2005). “[A] court should evaluate all the relevant circumstances in considering the factors ... [taking] into account all indicia negating as well as those suggesting fraud.” *Schempp*, 75 P.3d at 1162; *see also Blair*, 594 B.R. at 743 (“The exercise is holistic, and the Court should consider all the relevant circumstances.”); *Gen. Trading v. Yale Materials Handling Corp.*, 119 F.3d 1485, 1498–99 (11th Cir. 1997) (“[C]ourts take into account the particular facts surrounding the conveyance, and avoid determining in a vacuum the presence or absence ... actual intent to hinder or delay a creditor.”).

Plaintiffs allege four “badges” of fraud: (i) DBS was insolvent; (ii) the Subscriber Assignment was effectuated in connection with a transfer of all or substantially all of DBS’s assets, namely, the Intercompany Loan; (iii) the Transactions were made for no value or consideration; and (iv) the Transactions involved transferring assets to an “insider” under the statutory definition of the term. (Compl. ¶¶ 130, 146) These conclusory allegations are insufficient to state a claim.

a. Badge 1—Insolvency

Plaintiffs first allege that DBS was insolvent at the time of the Intercompany Loan Transaction and Subscriber Assignment. (*Id.* ¶¶ 76–77, 80) But the Complaint pleads no facts to support this assertion. Instead, Plaintiffs allege, “on information and belief,” that DBS has liabilities in excess of its assets. (*Id.* ¶¶ 80–84, 138, 153) Pleadings based on “information and belief” cannot satisfy the heightened pleading standard for the “badge” of insolvency. *Waite v.*

¹⁶ The “badges” include whether: (a) the transfer or obligation was to an insider; (b) the debtor retained possession or control of the property after the transfer; (c) the transfer or obligation was disclosed or concealed; (d) the debtor had been sued or threatened with suit before the transfer; (e) it was all or substantially all the debtor’s assets; (f) the debtor absconded; (g) the debtor removed or concealed assets; (h) the consideration received was reasonably equivalent to the value of the asset transferred; (i) the debtor was insolvent or became insolvent shortly after the transfer; (j) it occurred shortly before or after a substantial debt; and (k) the debtor transferred the essential assets of the business to a lienor, who transferred the assets to an insider. *See* § 38-8-105(2).

Schoenbach, 10-cv-3439, 2010 U.S. Dist. Lexis 115470, at *17 (S.D.N.Y. Oct. 29, 2010) (“[A]llegations, made entirely on information and belief” that the “transfers were made without fair consideration” and “rendered Defendants insolvent...are conclusory allegations that are insufficient to withstand a motion to dismiss.”); *Sedoy v. JW Ventures, LLC*, 15-cv-02168, 2016 WL 8309768, at *2 (D. Colo. Dec. 23, 2016) (same); *Pernick v. Computershare Tr. Co.*, 136 F. Supp. 3d 1247, 1274-75 (D. Colo. 2015) (dismissing fraudulent transfer claim under CUFTA where allegations related to debtors’ insolvency were “little more than a bare recitation of the elements”).

Even under more lenient pleading standards, Plaintiffs’ allegations regarding solvency fail. In order to demonstrate a transferor’s insolvency under CUFTA, a plaintiff must sufficiently allege that, at the time of the transfer, the “[de]btor [was] generally not paying his debts as they become due,” or that “the sum of the debtor’s debts [was] greater than all of the debtor’s assets at a fair valuation.” § 38-8-103; *Richard Ellis*, 251 P.3d at 527. Plaintiffs fail to plead either standard.

First, the Complaint contains no allegations that DBS was not paying its debts at the time of the Transactions. The commentary to CUFTA explains that:

In determining whether a debtor is paying its debts generally as they become due, the court should look at more than the amount and due dates of the indebtedness[,] ... tak[ing] into account such factors as the number of debts, the proportion of those debts not being paid, the duration of the nonpayment, and the existence of bona fide disputes

§ 38-8-103(2), cmt. 2. Thus, the question is based “only on a simple factual inquiry: At the time of the alleged fraudulent transfers, was the [transferor] paying his debts as they became due, or not?” *Weinman v. Corwley*, 588 B.R. 605, 632 (Bankr. D. Colo. 2018). The Complaint actually pleads the opposite—Plaintiffs acknowledge that EchoStar and its affiliates used proceeds from an intercompany asset sale to satisfy almost \$1 billion in outstanding debt as recently as March

2024. (*See, e.g.*, Compl. ¶ 62)

Faced with these facts, Plaintiffs purport to rely on “market evidence” that DBS’s debts will not be repaid. (*Id.* ¶¶ 75–76, 85) This market evidence, which is limited to analysts’ reports issued by a single rating agency, S&P Global, does not support Plaintiffs’ claims:

- Two of the four reports were based on certain future assumptions regarding the effect of the pending Exchange Offers, neither of which was effectuated. (*Id.* ¶ 80 & n.16);
- The third report was issued in March 2024, *after* the Exchange Offers were terminated, and says nothing about whether DBS has liabilities in excess of its assets at the time of the Transactions two months earlier. (*Id.* ¶ 84 & n.23–26); and
- The fourth report was issued in June 2023, more than six months before the relevant Transactions. (*Id.* ¶ 18 & nn.19–20) Thus, this report has no bearing on DBS’s financial condition at the time of the Transactions, as required.¹⁷ § 38-8-103; *see also Richard Ellis*, 251 P.3d at 533–34 (solvency measured at time of contested transfer).

Second, the Complaint contains no allegations that the sum of DBS’s debts was greater than all of its assets. For this element, CUFTA requires a comparison of “the fair value of the debtor’s assets [against] the extent of its liabilities at the time of each contested transfer.” *Richard Ellis*, 251 P.3d at 533–34. Here, Plaintiffs do not allege *anything* about DBS’s specific debt obligations (focusing only on non-party DISH, which is not a borrower here), nor do they allege *anything* about DBS’s total asset base. Instead, the Complaint simply alleges, “on information and belief,” that DBS had liabilities in excess of its assets, which Plaintiffs claim can be seen in the trading prices of DBS’s debt and the reports issued by S&P at the time the Exchange Offers were announced. (Compl. ¶¶ 85, 138, 153) These conclusory statements and cherry-picked analysts’ reports do not satisfy the “balance sheet test” inquiry required under CUFTA. *Richard Ellis*, 251 P.3d at 532 (balance sheet method used for determining solvency under CUFTA).

¹⁷ The Complaint also claims that the June 2023 S&P Global report offered an opinion on the recovery coverage for holders of the DBS Bonds in the event another exchange offer were to occur. (Compl. ¶ 82 & n.20) Not only is that temporally impossible, as this S&P report was written seven months before the Exchange Offers, the report itself makes no such claim.

b. Badge 2—All Or Substantially All

Plaintiffs next allege that a badge of fraud exists because the Intercompany Loan Transaction involved “all or substantially all” of DBS’s assets. (Compl. ¶¶ 121–22) As discussed above, the Intercompany Loan is demonstrably not all or substantially all of DBS’s assets. (See § I(B)(2), *supra*) (noting that the Tranche A portion only involved 22% of DBS’s assets).

c. Badge 3—Reasonably Equivalent Value

Plaintiffs next claim that a badge of fraud exists because the Intercompany Loan Transaction and Subscriber Assignment provided “no value” to DBS or its creditors. (Compl. ¶¶ 70, 130, 146) Such conclusory recitations of the elements do not satisfy the particularity requirement under Rule 9(b). *In re Sharp*, 403 F.3d at 56. In any event, an assessment of whether DBS received reasonably equivalent value under CUFTA “requires an analysis of all the facts and circumstances surrounding the transaction ... look[ing] to the substance of a transaction rather than its form.” *Ciccarelli v. Guar. Bank*, 99 P.3d 85, 88 (Colo. App. 2004) (“Determination of reasonably equivalent value requires analysis of all the facts and circumstances surrounding the transaction.”); *cf. Mellon Bank v. Metro Comm’n, Inc.*, 945 F.2d 635, 646-47 (3d Cir. 1991) (indirect benefits evaluated for reasonably equivalent value). Thus, alleging that a transfer was made for “no value,” without considering the context of the Merger and the strategy underpinning the Transactions, is insufficient. *Ciccarelli*, 99 P.3d at 88; *see also Chesapeake Bank & Tr. Co. v. Feaga*, No. 09-cv-114, 2012 Colo. Dist. Lexis 2556, at *8 (Colo. Dist. Ct. Aug. 28, 2012) (“[T]he adequacy of the consideration is not dispositive as to whether the transfer was actually fraudulent.”).

Critically, when a transfer is made within the same corporate structure following a merger, as was the case here, there is *no* loss of value, because any decrease in DBS’s asset base resulted in an equal increase in the value of its wholly-owned subsidiary. Moreover, transfers between

corporate affiliates are typically only deemed to have been made for insufficient value or consideration in instances where there is a pending or forthcoming claim against the transferor, such that the transfer could support a finding that it was made with an intent to defraud. *See, e.g., Lippe v. Bairnco Corp.*, 249 F.Supp.2d 357, 383 (S.D.N.Y. Mar. 2003) (intercompany transfers more likely to be considered fraudulent if purposefully done to leave company unable to pay its debts); *see also Multibank, Inc. v. Access Global Cap. LLC*, 17-civ-3467, 2017 U.S. Dist. Lexis 199947, at *19–20 (S.D.N.Y. Dec. 4, 2017) (company aware of pending suits against transferor weigh in favor of finding fraudulent transfer). No such pending claims were present here at the time of the Transactions, nor does the Complaint allege that there were.

d. Badge 4—Transfers To “Insiders”

Plaintiffs state in conclusory fashion that the counterparties to the Intercompany Loan Transaction and Subscriber Assignment were “insiders” under the statutory definition of the term. (Compl. ¶¶ 72, 130, 146) Standing alone, this allegation is meaningless, because *every* corporate restructuring transaction definitionally involves transfers and assignments to insider corporate affiliates, so this badge alone does nothing to support Plaintiffs’ claims. *Ciccarelli*, 99 P.3d at 88 (fraudulent transfer requires consideration of all facts and circumstances concerning transaction).

B. Plaintiffs Fail To Plead Constructive Fraudulent Transfer

To plead a constructive fraudulent transfer under Sections 105(1)(b) and 106(1) of CUFTA, the Complaint must adequately plead that: (i) DBS’s remaining assets after the Transactions “were unreasonably small in relation to [each T]ransaction” *or* that DBS “[i]ntended to incur, or believed or reasonably should have believed that [it] would incur, debts beyond [its] ability to pay as they became due,” *see* § 38-8-105(1)(b); *and* (ii) DBS received a lack of “reasonably equivalent value” in exchange for the transferred assets, such that it rendered DBS insolvent as a result, to be measured as of the time of the transaction. § 38-8-106(1); *see also Richard Ellis*, 251 P.3d at 534.

Plaintiffs fail to satisfy any of these elements.¹⁸

1. Plaintiffs Do No Plead Unreasonably Small Assets Or Inability To Pay Debts

Section 105(1)(b) requires Plaintiffs to sufficiently allege either that DBS's remaining assets after the Transactions were "unreasonably small," or that the Transactions rendered DBS unable to pay its debts as they came due. Plaintiffs plead nothing more than a verbatim recitation of the statutory language, (Compl. ¶¶ 137, 152), which is insufficient.

a. "Unreasonably Small Assets"

Section 105(1)(b)(I) focuses on the transferor's line of business and considers whether, after the subject transaction, the transferor's remaining assets were "unreasonably small" in relation to the transferred assets. *Blair*, 594 B.R. at 758. "The unreasonably small assets test...considers whether the transfer in question left the debtor with an 'inability to generate sufficient profits to sustain operations.'" *Richard Ellis*, 251 P.3d at 531. "[C]ourts consider whether the transfer put the debtor on 'the road to ruin'...or whether it left 'the transferor technically solvent but doomed to fail.'" *Id.*¹⁹

Plaintiffs do not allege that DBS is unable to generate sufficient profits or was steered onto a "road to ruin" by the Transactions, nor could they because DBS retained consolidated assets in excess of \$16 billion following the Transactions, or more than 57% of the pre-Transaction asset base. The Complaint, therefore, fails to satisfy Section 105(1)(b)(I).

b. "Debts Beyond The Ability To Pay"

Section 105(1)(b)(II) "measures whether the debtor, as a going concern, would reasonably

¹⁸ Similar to the actual constructive fraud claims, Plaintiffs' constructive fraud claims are not brought on account of the Spectrum Transfer or the Sling TV Designation, despite weaving in allegations about the purported "harm" these Transactions caused to other bondholders who did not elect to join this lawsuit. (*See, e.g.*, Compl. ¶¶ 65-69)

¹⁹ Although the Complaint's allegations regarding DBS's solvency fail to satisfy Section 106(1) or the "badges of fraud" under Section 105(2)(ii) (*see* § II(A)(2)(a), *supra*), "[t]he unreasonably small assets test is not the same as the test for insolvency" under these provisions. *Richard Ellis*, 251 P.3d at 531. Plaintiffs fail under either provision.

have been seen as able to pay its debts after making the [subject] transfer.” *Richard Ellis*, 251 P.3d at 532. “This does not mean that a debtor accumulated debts beyond the total of [its] assets, or that [it] could not immediately pay his or her debts in full. Rather, this test focuses on whether the debtor could reasonably pay debts as they came due” at the time of the transaction. *Id.* at 533.

Plaintiffs do not allege that DBS was rendered incapable of paying its debts as they came due. Instead, Plaintiffs rely on their own unsubstantiated speculation that DBS may have insufficient funds to pay future debts as they come due, based on the S&P Global reports. But the S&P Global reports’ opinions as to DBS’s ability to pay its future debts were premised on the effect of the Exchange Offers, neither of which occurred. Thus, these reports cannot support Plaintiffs’ claims. *Richard Ellis*, 251 P.3d at 535–36 (claim as to company’s solvency based on “uncertain” future events improper inquiry); *Johnson v. Brettmann*, 2020-cv-33373, 2020 Colo. Dist. Lexis 4740, at *16-17 (Colo. Dist. Ct. Dec. 22, 2020) (dismissing CUFTA claim in part because of failure to allege that debtor would be unable to pay plaintiff’s debt after subject transfers); *see also Dynegy*, 2011 Del. Ch. Lexis 113, at *68 (transactions that would not render company insolvent insufficient).

2. Plaintiffs Do Not Plead Lack Of Reasonably Equivalent Value

A complaint must also allege sufficient facts to show such a lack of “reasonably equivalent value” that the transferor was rendered insolvent. *See* § 38-8-106(1). Solvency under this inquiry is identical to what is required for actual fraud, considering whether “the sum of the [transferor’s] debts is greater than all of the [transferor’s] assets at a fair valuation.” *Richard Ellis*, 251 P.3d at 532; *see also Blair*, 594 B.R. at 753 (insolvency under CUFTA requires demonstration that transferor was “generally not paying his debts as they become due”). However, “[r]easonably equivalent value ... is not wholly synonymous with market value and it depends upon an analysis of all the facts and circumstances... includ[ing] both direct and indirect benefits to the transferor.”

Lev. Leading Co. v. Smith, 143 P.3d 1164, 1166 (Col. App. 2006).

Here, the Complaint focuses on each Transaction in a vacuum, maintaining that the statutory requirements have been met simply because DBS received “no value at all” in return. (*See, e.g.*, Compl. ¶¶ 67, 70, 130, 146) But an inquiry into whether DBS received dollar-for-dollar “value” as part of the Transactions ignores the context in which the Transactions were made (as part of a corporate reorganization following a corporate merger) and for what purpose (to effectuate the integration of the EchoStar and DISH business). It also ignores the “benefits” to DBS, as transfers made within the same corporate structure do not result in any “loss” in value from a transferred asset because they create a corresponding value “gain” elsewhere within the same structure. *See, e.g., Dynegy*, 2011 Del. Ch. Lexis 113, at *65–66 (no transfer of assets under UFTA when transferor retained same value and the transactions improved transferor’s ability to meet its financial obligations); *see also Johnson*, 2020 Colo. Dist. Lexis 4740, at *16-17 (dismissing CUFTA claim that did “not even attempt to aver why the[] transfers were made”). This is particularly the case in the Subscriber Assignment, where DBS has retained 100% of the value of the three million subscribers that are now with DBS Issuer. Plaintiffs’ remaining allegations that DBS had liabilities in excess of its assets are again premised only on “information and belief” (Compl. ¶¶ 80–84, 138, 153), which is insufficient. *Waite*, 2010 U.S. Dist. Lexis 115470, at *17 (dismissing CUFTA claim that did “not even attempt to aver why the[] transfers were made ...[forcing] speculat[ion]” about lack of reasonably equivalent value); *Pernick*, 136 F. Supp. 3d at 1274 (dismissing CUFTA claim where bare allegations “d[id] not support a plausible inference that [the transferor] did not receive reasonable equivalent value”).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss the Complaint with prejudice, and grant such further relief as the Court deems proper.

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New York, N.Y.

Respectfully submitted,

/s/ Glenn M. Kurtz

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EXHIBIT 54

Filed Under Seal