#### SIDLEY AUSTIN LLP

Thomas R. Califano (TX Bar No. 24122825)

William E. Curtin (*pro hac vice* pending) Anne G. Wallice (*pro hac vice* pending)

787 Seventh Avenue New York, NY 10019

Telephone: (212) 839-5300 Facsimile: (212) 839-5599

Email: tom.califano@sidley.com

wcurtin@sidley.com anne.wallice@sidley.com

Proposed Attorneys for the Debtors and Debtors in Possession

#### SIDLEY AUSTIN LLP

Charles M. Persons (TX Bar No. 24060413)

2021 McKinney Avenue, Suite 2000

Dallas, Texas 75201

Telephone: (214) 981-3300 Facsimile: (214) 981-3400

Email: cpersons@sidley.com

# IN THE UNITED STATES BANKRUPTCY COURT FOR THE NORTHERN DISTRICT OF TEXAS DALLAS DIVISION

In re:

EIGER BIOPHARMACEUTICALS, INC., et

 $al.^1$ 

Debtors.

Chapter 11

Case No. 24-80040 (SGJ)

(Joint Administration Requested)

# DECLARATION OF DAVID APELIAN IN SUPPORT OF THE CHAPTER 11 PETITIONS AND FIRST DAY PLEADINGS

I, David Apelian, M.D., hereby declare under penalty of perjury as follows:

1. I am the Chief Executive Officer ("<u>CEO</u>") of Debtor Eiger Biopharmaceuticals, Inc. ("<u>Eiger</u>"), the ultimate parent of each of the debtors and debtors in possession in the above-captioned chapter 11 cases (collectively, the "<u>Debtors</u>" or the "<u>Company</u>"). I am over the age of

The Debtors in these chapter 11 cases, together with the last four digits of each Debtor's federal tax identification number, are: Eiger BioPharmaceuticals, Inc. (1591); EBPI Merger Inc. (9986); EB Pharma LLC (8352); Eiger BioPharmaceuticals Europe Limited (N/A); and EigerBio Europe Limited (N/A). The Debtors' service address is 2155 Park Boulevard, Palo Alto, California 94306.



18 and authorized to submit this first day declaration (this "<u>Declaration</u>") on behalf of each of the Debtors.

- 2. I served as interim CEO of Eiger from December 2022 until June 2023, when I was appointed as CEO. I previously acted as Chief Operating Officer and Executive Medical Officer of Eiger from January 2018 to June 2019. I then briefly served as CEO of BlueSphere Bio, Inc. from July 2019 to October 2022, prior to transitioning to my role as interim CEO of Eiger. I have also served as a board member at Eiger since June 2017. I have over 25 years of clinical development and regulatory experience relating to pharmaceutical products, serving in numerous leadership roles throughout this time for various companies. Prior to my time at Eiger, I served as executive vice president and chief medical officer of Achillion Pharmaceuticals, Inc., where I was responsible for creating a portfolio strategy, managing the company's clinical development programs, and securing an instrumental partnership for Achillion. I also served as Clinical Bristol-Myers Director and Medical Leader at Squibb for the development Baraclude® (entecavir), a treatment for chronic hepatitis B virus. Prior to that, I served as Clinical Director in the Department of Hepatology & Gastroenterology at Schering Plough, where I coordinated a supplemental new drug application filing for the treatment of certain chronic conditions. I hold a PhD in Biochemistry from Rutgers University, an MD from the University of Medicine and Dentistry of New Jersey, an MBA from Quinnipiac University, and a bachelor's degree in Biochemistry from Rutgers University. I completed my residency training in pediatrics at New York Hospital, Cornell Medical Center, and was previously board certified in Pediatrics.
- 3. In my capacity as CEO of Eiger, I am familiar with the facts and circumstances set forth herein, which, except as otherwise noted, are based on my actual knowledge as well as information and advice provided to me by the Company's management and certain of its

professionals and advisors. In addition, the statements made herein are based, in whole or in part, upon my review of public and non-public documents and my discussions with other members of Eiger's management team and advisors on whom I have relied. I am generally familiar with Eiger's businesses, financial condition, day-to-day operations, and the circumstances leading to the commencement of these chapter 11 cases (the "Chapter 11 Cases). I believe, to the best of my knowledge, that the facts and circumstances set forth herein are true and correct. References to bankruptcy, the chapter 11 process, and related legal matters are based on my understanding of such in reliance on the explanation provided by counsel to Eiger. If called upon to testify, I would testify competently to the facts set forth herein.

- 4. On April 1, 2024 (the "Petition Date"), each of the Debtors commenced a voluntary case under chapter 11 of title 11 of the United States Code (the "Bankruptcy Code") in the United States Bankruptcy Court for the Northern District of Texas (the "Court"). As described herein, the Debtors filed these cases to transition their important, life-saving products to buyers who could ensure a stable supply of these products to patients and who could continue to develop other important drugs which the Debtors have in various stages of FDA approval. Because of defaults declared by their secured lender Innovatus and the specter of resulting enforcement actions, the Debtors require the protection of this Court through that process.
- 5. I am submitting this Declaration for the purpose of apprising the Court and other parties in interest of the history of the Debtors, their capital structure and debt, the circumstances that led to the commencement of these Chapter 11 Cases, and the motions and other applications filed with the Court, including the "first day motions" (the "<u>First Day Motions</u>").
- 6. To better assist the Court, this Declaration is organized in four sections. Part I provides background information on the Debtors' corporate history, operations, and assets, as well

as an overview of the pharmaceutical market. Part II outlines the Debtors' capital structure and other debt obligations. Part III describes the circumstances leading to the filing of these Chapter 11 Cases. Part IV sets forth the evidentiary basis for each of the First Day Motions and expresses the Debtors' belief that the Court should approve the same.

## **INTRODUCTION**

- 7. The Company is a commercial-stage biopharmaceutical company focused on the development of innovative therapies for rare diseases, and all of the Debtors' rare disease programs have FDA Breakthrough Therapy designation. The Debtors focus on developing and commercializing first-in-class, well-characterized drugs for life-threatening, rare and serious diseases with high unmet medical needs and no approved therapies. The Company filed these chapter 11 cases for two primary reasons: (1) to ensure stability and continuity in the provision of life-saving drugs for patients, including children, worldwide and (2) to institute a sale process designed to maximize the value of all the Debtors' assets for the benefit of all the Debtors' stakeholders. The Company takes it duties and responsibilities owed to the patients and its stakeholders with the utmost seriousness and believes that the chapter 11 process provides the least disruption and greatest accretive value to all parties.
- 8. As set forth below, the lead Debtor—Eiger BioPharmaceuticals, Inc.—is a NASDAQ listed company whose stock trading price indicates that it is likely to be solvent. Accordingly, the Debtors must consider the interests of all constituents—patients, shareholders and creditors through this process.
- 9. In an effort to continue the sale process that began in late 2023 and to maximize the value of the Company's assets on an expedited basis, the Debtors have filed a motion (the "<u>Bid Procedures Motion</u>") contemporaneously with their First Day Motions seeking, among other things, approval of a stalking horse purchase agreement (the "<u>Stalking Horse APA</u>") with Sentynl

Therapeutics, Inc. ("Sentynl" or the "Stalking Horse Purchaser") for the acquisition and sublicense of the Zokinvy assets (the "Zokinvy Sale Transaction") at a purchase price of \$26 million if the Zokinvy Sale Transaction closes (the "Closing") no later than April 24, 2024, provided, however, that for every day after April 24, 2024 that Closing does not occur, stalking horse bid decreases by an amount equal to \$214,285.71 (the "Zokinvy Stalking Horse Bid"), as further explained in the Apelian Bid Procedures Declaration filed concurrently herewith. The purchase price reduction reflects Zokinvy's revenue generating capability and, as time passes, the revenue that the ultimate purchaser would not recoup through the purchase. In any event, the Stalking Horse Bid encompasses a minimum purchase price of \$20 million, provided that the Zokinvy Sale Transaction closes no later than May 31, 2024. Originally, the Debtors and Sentynl were negotiating the terms of an out-of-court Zokinvy Sale Transaction, but Sentynl has now agreed to serve as Stalking Horse Purchaser, with the Stalking Horse Bid subject to higher or otherwise better offers in accordance with the proposed bidding procedures (the "Bidding Procedures").

10. The Bidding Procedures will also formalize a process for a sale of the Company's other assets, including Lonafarnib (HDV), Avexitide, and Lambda (respiratory) (including the Zokinvy Sale Transaction, the "Sale Transaction(s)"). The Bid Procedures Motion, subject to the Court's approval, will facilitate a competitive auction process, allowing all interested parties the opportunity to bid for the Debtors' assets. The Debtors received significant interest in their assets

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<sup>&</sup>lt;sup>2</sup> The "<u>Apelian Bid Procedures Declaration</u>" refers to the *Declaration of David Apelian in Support of the Debtors'* Motion for Entry of an Order (I)(A) Approving the Bid Procedures; (B) Authorizing the Debtors to Select Sentynl Therapeutics, Inc. as the Stalking Horse Purchaser & Approving Bid Protections; (C) Approving the Bid Protections Relating to the Remaining Assets Stalking Horse Purchaser(s), if any; (D) Establishing Bid Deadlines, Auction(s), and Sale Hearing(s); (E) Approving the Form and Manner of Sale Notice; (F) Approving Assignment and Assumption Procedures; (G) Approving the Form and Manner of Potential Assumption and Assignment Notice; (II)(A) Authorizing the Sale of the Assets Free and Clear; and (B) Approving the Assumption and Assignment of Designated Contracts; and (III) Granting Related Relief.

prior to these Chapter 11 Cases, and the Bidding Procedures will bring uniformity and control to a process designed to maximize value for all of the Debtors' stakeholders.

11. The Debtors' proposed timeline for these cases is intended to avoid the operational disruption and administrative burden of an uncontrolled or lengthy process balanced with providing sufficient time to identify appropriate buyers and create a competitive process. The Debtors cannot risk potential harm to the supply chain for patients that are reliant on these drugs. The Bid Procedures Motion seeks to balance the need to both maximize value, while limiting any disruption to commercialized products or delay to advancement of drugs in development.

## I. BACKGROUND

## A. Corporate Structure and History.

12. Eiger was founded in 2008 as a privately-held biopharmaceutical company focused on bringing to market novel products and "orphan drugs" for the treatment of rare diseases.<sup>3</sup> In March 2016, the privately-held Eiger completed a business combination with Celladon Corporation ("Celladon"), a biotechnology company historically focused on the development of cardiovascular gene therapy, in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated as of November 18, 2015. Pursuant to the Merger Agreement, Eiger acquired a wholly-owned subsidiary of Celladon, with Eiger surviving as a wholly-owned subsidiary of Celladon. Immediately following the merger, on March 23, 2016, Celladon changed its name to "Eiger BioPharmaceuticals, Inc." and Celladon's existing common stock began trading on The Nasdaq Global Market ("Nasdaq") under the ticker symbol "EIGR."

## 13. An organizational chart of the Company is attached hereto as **Exhibit A**.

<sup>&</sup>lt;sup>3</sup> Orphan drugs are drugs intended to treat rare diseases or conditions. According to the FDA, a disease is classified as a "rare" disease if it affects less than 200,000 people in the United States.

<sup>&</sup>lt;sup>4</sup> Celladon completed its initial public offering ("<u>IPO</u>") of its common stock in February 2014 and began trading on the Nasdaq shortly thereafter under the symbol "CLDN."

14. As of the Petition Date, the Company employs approximately nine full-time employees across the United States and Europe. The majority of the employees are engaged in manufacturing, research and development activities, while the remaining employees are engaged in general management and administration of the business. None of the Company's employees are represented by a labor union or subject to collective bargaining agreements.

#### B. Overview of the Pharmaceutical Industry.

- 15. The biopharmaceutical industry is highly competitive. There are many major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, public and private universities, and research organizations actively engaged in research and development of product candidates which may target the same markets as the Company's products.
- 16. Government authorities in the United States, at the federal, state, and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, requires substantial time and financial resources.
- 17. All of the Company's current products and product candidates are subject to regulation in the United States by the Food and Drug Administration (the "<u>FDA</u>") under the Federal Food, Drug, and Cosmetic Act. The FDA imposes extensive pre- and post-market regulation of any new drugs and the approval process is rigorous and inherently uncertain. Product development in the United States is comprehensive and typically involves a number of steps, including: (i) completion of preclinical laboratory and animal tests, submission to the FDA of an

investigational new drug application, which must become effective before clinical testing may commence, (ii) approval by an independent institutional review board at each clinical site before each trial may be initiated, (iii) performance of adequate and well controlled clinical trials to establish the safety, efficacy, purity and/or potency of the product for each indication for which FDA approval is sought, (iv) submission to the FDA of a new drug application ("NDA") or biologics license application ("BLA"), (v) satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced, and (vi) FDA review and approval of the NDA or BLA. Clinical trials to support an NDA or BLA for marketing approval are typically conducted in three sequential phases:

- <u>Phase 1</u>: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition, and is tested to assess safety, dosage tolerance, pharmacokinetics and pharmacological activity, and, when possible, to ascertain evidence of efficacy;
- <u>Phase 2</u>: The trials are conducted using a limited patient population for the purposes of preliminarily determining the effectiveness of the product in that particular indication, ascertaining dosage tolerance, discerning the optimal dosage, and identifying possible adverse effects and safety risks; and
- Phase 3: Phase 3 clinical trials are undertaken to obtain additional information from an expanded and diverse patient population, at multiple, geographically dispersed clinical trial sites, in randomized controlled studies often with a double-blind design to maximize the reproducibility of the study results. These trials are intended to provide sufficient data demonstrating evidence of the safety, efficacy, purity and potency of the product such that the FDA can evaluate the overall benefit-risk of the product and provide adequate information for the labeling and package insert for the product.
- 18. Notwithstanding this time-intensive and rigorous approval process, the FDA offers several expedited development and review programs for qualifying product candidates, such as the Fast Track program, which expedites the process for reviewing new products that are intended to treat serious or life-threatening diseases and demonstrate the potential to address such unmet

needs, and breakthrough therapy designation ("Breakthrough Therapy Designation"), which similarly expedites the process for products that are intended to treat serious or life-threatening diseases, but also requires preliminary clinical evidence indicating that such product may be effective.

- 19. Further, the FDA may grant products intended to treat a rare disease or condition an Orphan Drug designation ("Orphan Drug Designation"). While Orphan Drug Designation does not abridge the timeline for regulatory review and approval process, it does entitle the first grantee to be approved to treat a disease with FDA's Orphan Drug Designation a seven-year period of marketing exclusivity in the United States for that product, as well as certain tax credits for research expenses and a waiver of the application user fee.
- 20. While the FDA regulates any new drugs in the United States, a similar entity—the European Medicines Agency (the "EMA")—serves as an analogous regulatory body for all European Member states, as well as Iceland, Liechtenstein, and Norway. Like the FDA, the EMA will also grant Orphan Drug Designation to qualifying products for the treatment, prevention, or diagnosis of life-threatening or chronically debilitating conditions. Further, in many ways, the EMA's Priority Medicine Scheme ("PRIME") mirrors the FDA's Breakthrough Therapy Designation by conferring comparable benefits on qualifying drug product candidates.

# C. Overview of the Company's Business, Products, and Assets.

21. The Company has currently has one FDA-approved product on the market and has others in clinical trial stages, each as described in further detail below.

Advancing Targeted Therapies for Rare Diseases							
Indication	Program	Status	Phase 2	Phase 3	Approved		
Progeria	Zokinvy	Generating Revenue					
Post-Bariatric Hypoglycemia (PBH)	Avexitide	Phase 3 Ready					
Congenital Hyperinsulinism (HI)		Phase 3 Ready					
Hepatitis Delta Virus (HDV)	Lonafamib/Ritonavir	On Hold					
	Peginterferon Lambda	On Hold					

## i. Products and Clinical Studies.

## 1. Lonafarnib

- 22. Lonafarnib ("LNF") is an orally bioavailable, first-in-class farnesylation inhibitor originally developed by Merck & Co. ("Merck") that the Company has an exclusive license to develop and commercialize, as discussed in further detail below. In November 2020, the Company received FDA approval for the use of LNF to reduce the risk of mortality of Hutchinson-Gilford progeria syndrome ("HGPS") and for treatment of processing-deficient progeroid laminopathies ("PL"), collectively known as "progeria," an ultra-rare and rapidly fatal genetic condition causing accelerated aging in children. Sold under the brand name "Zokinvy," the medication is the Company's first and only product that has received FDA approval.
- 23. The Company commercially launched Zokinvy in the United States in January 2021 and began generating product revenue shortly thereafter. International regulatory approvals

<sup>&</sup>lt;sup>5</sup> Published studies demonstrate that farnesylation inhibitors block HDV viral production. Targeting farnesylation or farnesyltransferase, a host target, significantly reduces the likelihood of HDV developing resistance to escape effects of antiviral therapy. *See* Eiger BioPharmaceuticals, Inc., Annual Report (Form 10-K) (Mar. 13, 2023).

followed beginning in May 2022, with the Pharmaceutical Division at The Ministry of Health of Israel granting regulatory approval for Zokinvy. Then, in July 2022, the Company received marketing authorization under exceptional circumstances for Zokinvy for the treatment of progeria in all 27 European Union member states plus Iceland, Liechtenstein, and Norway. The marketing authorization is valid for five years from date of authorization and is subject to annual reassessment of the benefit/risk profile based on the requirements set forth in the marketing authorization. In August 2022, the United Kingdom's Medicine and Healthcare Products Regulatory Agency granted the Company marketing authorization of Zokinvy.

- 24. Moreover, the Company continues to receive international regulatory approvals related to the marketing of Zokinvy. In May 2022, the Company entered into a Marketing and Distribution Agreement (the "MDA") with AnGes, Inc. ("AnGes"), a company in Japan, whereby the Company bestowed upon AnGes a right to use the Company's intellectual property and seek regulatory approval for commercialization of Zokinvy in Japan. In January 2024, AnGes received such marketing approval for Zokinvy from the Ministry of Health, Labour, and Welfare in Japan for the treatment of HGPS and PL. Accordingly, pursuant to the MDA, AnGes now holds the marketing authorization for Zokinvy in Japan and is responsible for all regulatory interactions. In turn, AnGes is required to pay the Company \$1.5 million upon achieving certain precommercialization milestones.
- 25. Upon licensing LNF from Merck, the Company also began researching alternative uses of LNF and found a potentially viable solution for the treatment of hepatitis delta virus ("HDV"), 6 the most severe form of viral hepatitis for which there is currently no FDA-approved

<sup>&</sup>lt;sup>6</sup> Chronic HDV infection can lead to a rapid progression to liver cirrhosis, a greater likelihood of developing liver cancer, and has the highest fatality rate of all the chronic hepatitis infections.

therapy. The Company's treatment involves combining LNF with ritonavir, an antiretroviral medication, in order to reduce HDV's viral load. LNF for treatment of HDV infection has been granted Orphan Drug designation by the FDA and EMA, Fast Track and Breakthrough Therapy Designations by the FDA and PRIME designation by the EMA.

26. In June 2023, the Company completed its Phase 3 study (the "<u>D-LIVR Study</u>") for the use of LNF on patients with chronic HDV and concluded that the drug exhibited a statistically significant likelihood of efficacy. At a pre-NDA meeting with the FDA, the regulatory agency expressed that it was supportive of a potential path to an NDA approval for LNF-based regimens for the treatment of HDV.

#### 2. Avexitide

- Avexitide is a well-characterized peptide in development for the treatment the treatment of post-bariatric hypoglycemia ("PBH") and other forms of hyperinsulinemic hypoglycemia ("HH") arising after gastrointestinal surgeries. These disorders are characterized by exaggerated secretion of GLP-1 after meals, dysregulated secretion of insulin, followed by a rapid drop in blood sugar. Avexitide is the only drug in development for PBH with Breakthrough Therapy designation by the FDA. Avexitide is also in development for congenital hyperinsulinism ("HI"), an ultra-rare, life-threatening, pediatric disorder of persistent hypoglycemia that results in irreversible brain damage in up to 50% of children with the condition. For both PBH and HI, Avexitide has completed Phase 2 and is ready for Phase 3.
- 28. Avexitide has been granted Breakthrough Therapy designation by the FDA for the treatment of HI, Orphan Drug designation by the EMA for the treatment of HI and Orphan Drug designation by the FDA for the treatment of hyperinsulinemic hypoglycemia, which includes HI.

Avexitide has also been granted Rare Pediatric Disease designation by the FDA for the treatment of HI. *Peginterferon Lambda* 

- 29. The Company licensed worldwide rights to Peginterferon Lambda ("<u>Lambda</u>"), a well-tolerated interferon that stimulates immune responses critical for the development of host protection during viral infections, from Bristol Myers Squibb Company ("<u>Bristol</u>") in April 2016. Concurrently with its efforts to utilize LNF for the treatment of HDV, the Company sought to develop a separate treatment utilizing Lambda for the treatment of HDV.
- 30. In the early stages of its development, Lambda for the treatment of HDV infection received Orphan Drug designation from the FDA and the EMA and Fast Track and Breakthrough Therapy designations from the FDA. Due to the initially promising results in Phase 2 of the Company's study, the FDA and EMA authorized a single pivotal, randomized Phase 3 study of Lambda as a monotherapy for treatment of HDV (the "LIMT Study," and together with the D-LVR Study, the "HDV Development Programs").
- 31. Along with the LIMT Study, the Company began exploring opportunities to use Lambda to treat COVID-19 and other viral respiratory infections. Early studies suggested potential efficacy in this domain and the Company remains open to further strategic development.
- 32. In September 2023, following its quarterly safety review, the Data Safety Monitoring Board (the "DSMB") observed four patients in the LIMT Study with hepatobiliary events that resulted in liver decompensation. Shortly thereafter, the Company announced its decision to discontinue Phase 3 of its LMIT Study, citing recommendations from the DSMB and FDA as the reason for such cessation. Regardless, the Company believes that Lambda may have potential uses for development in hepatitis B virus (HBV), respiratory diseases such as COVID-19 and influenza, as well as other virology indications.

## ii. Manufacturing and Supply.

33. The Company does not own or operate manufacturing facilities for the production of its products, nor does it have any plans to build such facilities. Therefore, the Company heavily relies on third parties for the commercial manufacturing of Zokinvy and all of its clinical product candidates. The Debtors have manufacturing agreements certain contract manufacturing organizations ("CMOs") that manufacture the Debtors' products under the supervision of the Debtors' personnel.

# iii. Research and Development.

34. Research and development is the foundation upon which the Company is built, and therefore, the Company invests heavily in this area. Historically, the largest component of the Company's operating expenses has been the investment in clinical trials, including contract manufacturing arrangements, clinical trial material related costs, and other research and development activities. In 2023, the Company's research and development expenses for the year were approximately \$62.3 million. Notably, however, this number reflects an approximate \$13 million decrease compared to the same period in 2022, due in large part to a decline in expenditures related to the HDV Development Programs, and a decrease in the use of consulting and advisory services, and a reduction of Company personnel.

#### iv. Intellectual Property and License Agreements.

35. The Company has sought to protect its proprietary position by, among other methods, pursuing and obtaining patent protection in various jurisdictions related to its proprietary technology, inventions, improvements, platforms, and product candidates that are important to the development and implementation of its business. The Company's patent portfolio is intended to cover, but is not limited to, its product candidates and components thereof, their methods of use

and processes for their manufacture, and any other inventions that are commercially important to the Company's business. Further, the Company has rights to intellectual property, through licenses from third parties and under patents that the Company does not own, to develop and commercialize certain product candidates.

## 1. The Merck License.

- 36. In September 2010, the Company entered into an exclusive license agreement (the "Merck Agreement") with Schering Corporation, subsequently acquired by Merck, which provided the Company with the exclusive right to develop and commercialize LNF (such license, the "Merck License"). The Company is obligated to pay Merck up to an aggregate of \$27.0 million in development milestones and is required to pay tiered royalties based on aggregate annual net sales of all licensed products, ranging from mid-single to low double-digit royalties on net sales. This obligation expires on a country-by-country and product-by-product basis on the later of the expiration of the last to expire patent assigned to the Company under the Merck Agreement on the tenth anniversary of the first commercial sale of the product.
- 37. On May 15, 2018, the Company entered into an amendment to the Merck Agreement (the "<u>First Merck Amendment</u>"), which provided for expansion of the existing exclusively licensed field of use under the Merck License to include all uses of LNF related to the treatment of HGPS at no cost to the Company. Pursuant to the First Merck Amendment, the Company has the sole responsibility and continuing obligation to manufacture and supply LNF to The Progeria Research Foundation ("<u>PRF</u>").
- 38. On November 3, 2020, the Company entered into a second amendment to the Merck Agreement, which expanded the definition of HGPS to also include progeroid laminopathies.

## 2. The PRF Collaboration Agreement.

39. Concurrently with its execution of the First Merck Amendment, on May 15, 2018, the Company entered into a Collaboration and Supply Agreement with PRF (the "PRF Collaboration Agreement"). Under the PRF Collaboration Agreement, PRF granted the Company a non-exclusive, world-wide, royalty-free, sub-licensable license pertaining to all intellectual property and data controlled by PRF to prepare and file any NDA for a product containing LNF for progeria. In exchange, the Company is subject to numerous requirements, including, but not limited to: (i) exclusively supplying LNF to PRF for use in clinical trials and non-clinical research in progeria, (ii) preparing and sponsoring any NDA submission for LNF for the treatment of progeria to the FDA, (iii) using commercially reasonable efforts to file an NDA for progeria according to a specified timeline, (iv) submitting certain FDA expedited approval requests in connection with an NDA filing, and (v) accepting responsibility for any additional studies necessary for obtaining an NDA for progeria.

#### v. Tax Credits.

40. Eiger has incurred significant net operating losses ("NOLs"). Further, the Company has earned tax credits related to research and development ("R&D Credits"), and Orphan Drugs ("Orphan Drug Credits," and, together with the NOLs and the R&D Credits, the "Tax Credits"). As of December 31, 2023, Eiger had generated federal NOLs of approximately \$322.5 million and state NOLs of approximately \$47.1 million. Eiger also had approximately \$1.6 million of federal R&D Credits and approximately \$4 million of state R&D Credits. Further, on account of its treatments that have received Orphan Drug Designation, Eiger has approximately \$15.5 million of federal Orphan Drug Credit carryforwards available. The Tax Credits are potentially of significant value as they may be used, under certain circumstances, to offset future taxable income

or federal tax liabilities in future years. Concurrently herewith, the Debtors have filed an emergency motion seeking to preserve the Tax Credits through a restriction on the transfer and sale of its stock.

#### II. PREPETITION CAPITAL STRUCTURE

41. As of the Petition Date, the amount outstanding under the Innovatus Loan (as defined below) is approximately \$41.7 million, as follows:

	<u>Principal</u>	<u>Interest</u>	<u>Total</u>
Term A	\$41,685,030.30	\$0	\$41,685,030.30
Term B <sup>7</sup>	\$0	\$0	\$0
Term C <sup>8</sup>	\$0	\$0	\$0
Total	\$41,685,030.30	\$0	\$41,685,030.30

#### A. Secured Debt.

42. On June 1, 2022, certain of the Debtors entered into a loan and security agreement (the "Loan and Security Agreement") with Innovatus Life Sciences Lending Fund I, LP ("Innovatus" or the "Prepetition Term Loan Lenders"), providing for up to \$75 million funded in three tranches with a maturity date of August 31, 2027 (the "Innovatus Loan"). The floating per annum interest rate of the Loan and Security Agreement is equal to the sum of (a) the greater of (i) the Prime Rate published in the Money Rates section of the Wall Street Journal (or any successor thereto) and (ii) 3.5%, plus (b) 3.75%; provided that, at the election of the Company, up to 2.25% of such rate shall be payable in-kind until the third anniversary of the closing date. As of December 31, 2023, the effective interest rate for the Innovatus Loan is 13.84%.

<sup>&</sup>lt;sup>7</sup> The Loan and Security Agreement provides for a Term B Draw (as defined in the Loan and Security Agreement) in an aggregate principal amount of up to \$17,500,000. No amounts were drawn under the Term B tranche.

<sup>&</sup>lt;sup>8</sup> The Loan and Security Agreement provides for a Term C Draw (as defined in the Loan and Security Agreement) in an aggregate principal amount of up to \$17,500,000. No amounts were drawn under the Term C tranche.

- 43. Under the Loan and Security Agreement, the Company is required to make monthly interest-only payments through July 1, 2027, after which the Company is required to make monthly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity. The Loan and Security Agreement is secured by perfected first priority liens on the Company's assets, including a commitment by the Company to not allow any liens to be placed upon the Company's intellectual property.
- 44. At closing, the Debtors were funded \$40 million under Term A, \$33.5 million of which was used to fully pay off a preexisting loan. The \$17.5 million under each of Term B and Term C became available on the later of (a) the first date that the Company achieves certain development and regulatory milestones applicable to each term and (b) November 1, 2022. Both Term B and Term C draw periods end on the earlier of (a) June 30, 2024 or (b) an event of default.

## B. Equity.

## 1. Common Stock.

45. Eiger's equity is publicly traded, with Eiger authorized to issue 200,000,000 shares of common stock. On January 5, 2024, Eiger effected a 1-for-30 reverse stock split (the "Reverse Stock Split") of its common stock, and, on January 8, 2024, Eiger's common stock began trading on a split adjusted basis. As of January 5, 2024, Eiger had 1,476,247 shares of common stock issued and outstanding. As of March 31, 2024, Eiger's common stock was trading at \$5.01.

## 2. Stock Purchase Agreement.

46. In connection with entry into the Loan and Security Agreement, the Debtors entered into a stock purchase agreement with Innovatus (the "Stock Purchase Agreement") for the sale of

common stock with an aggregate value of \$5 million. On June 1, 2022, the Debtors issued 749,053 shares of common stock at a per share purchase price of \$6.6751.9

## 3. Open Market Sale Agreement.

47. On March 25, 2022, the Company entered into an Open Market Sale Agreement with Jefferies Group LLC ("Jefferies"), pursuant to which the Company can sell up to a maximum of \$50.0 million of its common stock in offerings that are deemed "at the market" offerings as defined in Rule 415 under the Securities Act, under the Company's effective shelf registration statement (the "2022 ATM Facility"). In April 2022, the Company completed offerings from the 2022 ATM facility for a total of 2,686,288 shares of its common stock, <sup>10</sup> resulting in net proceeds of \$20.8 million, after deducting commissions costs. No additional offerings were completed since April 2022. The registration statement registering the offer and sale of shares pursuant to the 2022 ATM Facility expired in December 2023.

#### III. KEY EVENTS LEADING TO CHAPTER 11 FILING

48. As set forth in more detail below, the continuing cash drain on the Company and delays in achieving successful clinical trials for certain products, along with an inability to raise additional capital, required the Company to begin exploring strategic alternatives to address its goforward liquidity position. The Company engaged advisors to assist in these efforts, including Sidley Austin LLP ("Sidley"), as restructuring counsel, Alvarez & Marsal, as financial advisor, and SSG Advisors, LLC, as investment banker. After exploring various potential pathways, the Company ultimately determined to file these Chapter 11 Cases, all in an effort to maximize the value of its assets and operations for the benefit of its creditors and all parties in interest.

<sup>&</sup>lt;sup>9</sup> Or, as adjusted to reflect the January 2024 Reverse Stock Split, 24,967 shares of common stock to Innovatus at a per share price of \$200.25.

<sup>&</sup>lt;sup>10</sup> Or, as adjusted to reflect the January 2024 Reverse Stock Split, 89,539 shares of common stock.

#### A. Clinical Trials.

49. The Company's business depends, in large part, on its ability to obtain and maintain required regulatory approvals. Obtaining such regulatory approvals is no easy task, however, and if the Company receives approval at all, it is subject to the FDA's unspecified timeline. The Company faced significant setbacks when it received, and ultimately followed, the DSMB's recommendation to discontinue its Phase 3 LIMT Study for Lambda-based HDV treatments, despite initial indicators of efficacy in its Phase 1 and Phase 2 trials.

## B. Reductions in Force and Other Cost-Saving Measures.

- 50. Recognizing its strained liquidity position, the Company took actions to preserve its ability to continue operations in the ordinary course. In 2023, the Company reduced its workforce by 18 employees, representing approximately 46% of the Company's workforce. Since then, the Company has further issued reduction in force notifications to a total of 12 former employees (collectively, the "RIF"). Throughout this time, the Company carefully sought to balance the need to reduce costs with the need to maintain essential employees and operations. On account of the RIF, the Company incurred approximately \$1.2 million in compensation and personnel related expenses, including severance payouts for terminated employees.
- 51. The Company also undertook an extensive portfolio prioritization review in June 2023, determining to focus clinical development efforts on advancing avexitide in hyperinsulinemic hypoglycemia (HH) indications. As a result of the Company's decision to reprioritize its HDV Development Programs, the Company reduced its research and development expenses by approximately \$13 million as of December 31, 2023, consisting of a \$5 million decrease in milestone expenses related to the Lambda clinical studies under the License Agreement with Bristol, a \$3.5 million decrease in outside services across programs, including consulting and

advisory services, a \$3.3 million decrease in clinical and contract manufacturing expenses, and a \$1 million decrease in compensation and personnel related expenses.

# C. Exploration of Strategic Alternatives.

- 52. Since its inception, the Company has incurred operating losses, resulting in tight cash constraints. The Company had a net loss of approximately \$75 million and \$96.8 million for the years ended December 31, 2023 and 2022, respectively. As of the Petition Date, the Company has approximately \$9.9 million of cash on hand. Developing product lines is an intrinsically resource-intensive process, and the Company has relied historically on the sale of equity securities and debt facilities to fund their operations. Notwithstanding the Company's cost-reduction efforts, because of the sustained operating losses, the Company recognized that additional financing was likely necessary to support ongoing development and commercialization.
- Bio Management, LLC ("Propel"), one of its institutional shareholders, attempted to negotiate the terms of a potential investment, which would be used for the development of LNF for the treatment of HDV. Unfortunately, the investment proposal was not actionable, despite months of negotiation, and the Company was forced to pivot to alternative options—specifically, focusing on the ability to potentially consummate a sale of Zokinvy to bring in needed revenue for debt reduction and operations.
- 54. The Company has engaged with the Stalking Horse Purchaser over the past six months, in parallel with its financing efforts. Initially, the sale was intended to be consummated outside of Court, but, as the Company's circumstances evolved and, with the loss of the potential investment, the Company worked with the Stalking Horse Purchaser to pivot to an in-court transaction, as is further described in the Bid Procedures Motion.

55. The Bidding Procedures will allow the Company to market-test the assets and ensure that the Zokinvy Sale Transaction represents the highest and best value to all stakeholders.

# D. Engagement with Prepetition Term Loan Lenders.

- 56. Throughout the Company's efforts to reduce costs and pursue strategic alternatives, the Company has engaged with the Prepetition Term Loan Lenders on next steps. Specifically, the Company provided the Prepetition Term Loan Lenders and their counsel with ongoing updates related to the status of the ongoing negotiations for both the potential investment and Zokinvy Sale Transaction.
- 57. Notwithstanding these efforts, on January 17, 2024, the Prepetition Term Loan Lenders delivered a notice (the "<u>Default Notice</u>") to the Company, stating that, under the Loan and Security Agreement, an Event of Default (as defined in the Loan and Security Agreement) had occurred due to a Material Adverse Change (as defined in the Loan and Security Agreement), without providing additional details. The Company disputes the allegation that a Material Adverse Change had occurred and saw no basis for delivery of the Default Notice.
- 58. The Company's counsel engaged with the Prepetition Term Loan Lenders' counsel (Bradley Arant Boult Cummings, LLP ("Bradley")) to understand the basis of the Default Notice, and, following those conversations, the Company, through Sidley, responded to Bradley, disputing the Material Adverse Change and Event of Default claims. Following further discussions among the Company's and Prepetition Term Loan Lenders' counsel, the Prepetition Term Loan Lenders voluntarily initially agreed to forbear from exercising remedies under the Loan and Security Agreement until February 2, 2024, and have since continued to issue voluntarily forbearances, currently through April 3, 2024.

## E. Chapter 11 Filings and Next Steps.

- 59. The Debtors' ultimate goals in these Chapter 11 Cases are first, to ensure stability and continuity in the provision of life-saving drugs for progeria patients, including children, worldwide, and second, to consummate the Sale Transactions, thereby maximizing the value of the Debtors' estates for the benefit of all stakeholders.
- 60. The Debtors' immediate objective is to conduct these Chapter 11 Cases with as little disruption to operations as possible. I believe that, if the Court grants the relief requested in each of the First Day Motions, as discussed in more detail below, the prospect for achieving this objective and maximizing value for the benefit of all stakeholders will be substantially enhanced. Moreover, if the relief requested in the First Day Motions is not granted, the Debtors would suffer immediate and irreparable harm.

#### IV. FIRST DAY MOTIONS

- 61. In addition to the Bid Procedures Motion and contemporaneously herewith, the Debtors have filed a number of First Day Motions seeking orders granting various forms of relief intended to stabilize the Debtors' business operations, facilitate the efficient administration of these chapter 11 cases, and expedite a swift and smooth restructuring of the Debtors' balance sheet, including the following:
  - Debtors' Emergency Motion for Entry of an Order Directing Joint Administration of Chapter 11 Cases (the "Joint Administration Motion");
  - Debtors' Emergency Motion for Entry of an Order Extending Time to File Schedules of Assets and Liabilities and Statements of Financial Affairs (the "Schedules and SOFAs Motion");
  - Debtors' Emergency Application for Entry of an Order Authorizing the Retention and Employment of Kurtzman Carson Consultants LLC as Claims, Noticing and Solicitation Agent, Effective as of the Petition Date (the "KCC Retention Application");

- Debtors' Emergency Motion for Entry of an Order (I) Authorizing the Debtors to (A) File a Consolidated Creditor Matrix and (B) File a Consolidated List of 30 Largest Unsecured Creditors; (II) Waiving the Requirement to File a List of Equity Security Holders; (III) Authorizing the Debtors to Redact Certain Personally Identifying Information; and (IV) Approving the Form and Manner of Notifying Creditors of the Commencement of the Chapter 11 Cases and Other Information (the "Creditor Matrix Motion");
- Debtors' Emergency Motion for Entry of an Order (I) Authorizing the Debtors to (A) Continue Their Prepetition Insurance Coverage and Satisfy Prepetition Obligations Related Thereto and (B) Renew, Supplement, and Enter Into New Insurance Policies, and (II) Granting Related Relief (the "Insurance Motion");
- Debtors' Emergency Motion for Entry of Interim And Final Orders (I) Authorizing the Debtors to Honor And Continue Certain Customer Programs and Customer Obligations in the Ordinary Course of Business, and (II) Authorizing Banks to Honor and Process Check an Electronic Transfer Requests Related Thereto (the "Customer Programs Motion");
- Debtors' Emergency Motion for Entry of an Order (I) Approving the Debtors' Proposed Adequate Assurance of Payment for Future Utility Services, (II) Prohibiting Utility Companies From Altering, Refusing, or Discontinuing Services, and (III) Approving the Debtors' Proposed Procedures for Resolving Additional Assurance Requests (the "Utilities Motion");
- Debtors' Emergency Motion for Entry of an Order Approving Notification and Hearing Procedures for Certain Transfers of and Declarations of Worthlessness with Respect to Common Stock (the "NOL Motion");
- Debtors' Emergency Motion for Entry of Interim and Final Orders Authorizing the Debtors to Pay Certain Taxes and Fees (the "Taxes Motion");
- Debtors' Emergency Motion for Entry of an Order (I) Authorizing the Debtors to Pay Certain Prepetition Claims of (A) 503(B)(9) Claimants, (B) Lien Claimants, (C) Critical Vendors, and (D) Foreign Claimants, (II) Confirming Administrative Expense Priority of Outstanding Orders (the "Critical Vendors Motion");
- Debtors' Emergency Motion for Entry of an Order (I) Authorizing the Debtors to (A) Pay Prepetition Wages, Salaries, and Employee Benefits and (B) Continue the Postpetition Maintenance of Employee Benefit Programs, Policies, and Procedures in the Ordinary Course (the "Employee Wages Motion");
- Debtors' Emergency Motion for Entry of Interim and Final Orders (I) Authorizing the Debtors to Continue to Operate Their Cash Management System and Maintain Existing Bank Accounts, (II) Honor Certain Obligations Relating Thereto; and (III) Granting a Waiver of Certain Deposit and Investment Requirements in 11 U.S.C. § 345(b) and the UST Guidelines (the "Cash Management Motion"); and

- Debtors' Emergency Motion for Entry of Interim and Final Orders (I) Authorizing the Debtors to Use Cash Collateral; (II) Granting Adequate Protection to Prepetition Term Loan Secured Parties; (III) Modifying Automatic Stay; (IV) Scheduling a Final Hearing (the "Cash Collateral Motion").
- 62. Several of the First Day Motions request authority to pay certain prepetition claims. I understand that Federal Rule of Bankruptcy Procedure 6003 provides, in relevant part, that the Court shall not consider motions to pay prepetition claims during the first 21 days following the filing of a chapter 11 petition, "except to the extent relief is necessary to avoid immediate and irreparable harm." In light of this requirement, the Debtors have narrowly tailored their requests for immediate authority to pay certain prepetition claims to those circumstances where the failure to pay such claims would cause immediate and irreparable harm to the Debtors and their estates. Other relief will be deferred for consideration at a later hearing.
- 63. I have consulted with my colleagues at the Company and the Debtors' advisors regarding the relief requested in the First Day Motions, and understand each of the First Day Motions and the relief requested therein. To the best of my knowledge and belief, the factual statements contained in each of the First Day Motions are true and accurate, and each such factual statement is incorporated herein by reference.
- 64. I believe that the relief requested in the First Day Motions is necessary, in the best interests of the Debtors' estates, their patients, their creditors, shareholders, and all other parties in interest, and will allow the Debtors to operate with minimal disruption and maximize value preservation during the pendency of these Chapter 11 Cases. I further believe that failure to grant the relief requested in any of the First Day Motions may result in immediate and irreparable harm to the Debtors, their businesses, and their estates. Accordingly, for the reasons set forth herein and in each respective First Day Motion, I believe that the Court should grant the relief requested in each of the First Day Motions.

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I declare under penalty of perjury that, to the best of my knowledge and after reasonable inquiry, the foregoing is true and correct.

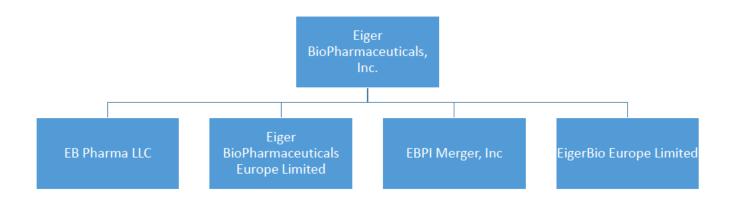
Dated this 1st day of April, 2024

/s/ David Apelian

David Apelian
Chief Executive Officer

# **EXHIBIT A**

# **Organizational Chart**



Eiger BioPharmaceuticals, Inc owns 100% of each subsidiary