IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	)	Chapter 11
	)	
Tricida, Inc., [1]	)	Case No. 23-10024 (JTD)
Debtor.	)	
	)	**Objection Deadline: September 1, 2023 at 4:00 p.m.**
	)	**Hearing Date: September 27, 2023 at 11:00 a.m.**

MOTION OF THE LIQUIDATING TRUSTEE TO SUBORDINATE CLAIM NO. 144 FILED BY JEFFREY FIORE, AS SECURITIES LEAD PLAINTIFF FOR A PROPOSED CLASS OF PLAINTIFFS, AND CLAIM NO. 146 FILED JEFFREY FIORE INDIVIDUALLY PURSUANT TO 11 U.S.C. § 510(B)

Jackson Square Advisors, as trustee (the "Liquidating Trustee") of the Tricida Liquidating Trust (the "Liquidating Trust"), by and through undersigned counsel, moves this Honorable Court for the entry of an order, pursuant to 11 U.S.C. § 510(b), subordinating claims of Jeffrey Fiore, as Securities Lead Plaintiff ("Lead Plaintiff") for a Proposed Class of plaintiffs and Jeffrey Fiore individually ("Fiore"). In support of its Motion, the Liquidating Trustee states as follows:

Preliminary Statement

1. The Lead Plaintiff and Fiore each filed a claim for damages arising from violations of Federal securities laws with respect to the issuance of Tricida's common stock. "11 U.S.C. § 510(b) subordinates claims for damages arising from the purchase or sale of a security of the debtor to all claims and interests that are senior or equal to the claim or interest represented by such security."[2] Where, as here, the security is common stock, these claims have the same priority as common stock.[3] Claims of shareholders alleging fraud in the issuance of common stock, such as

[1] The Debtor in this chapter 11 case, together with the last four digits of the Debtor's federal tax identification number, is Tricida, Inc. (2526).

[2] *In re Integrated Telecom Express, Inc*., 384 F.3d 108, 117, FN 2 (3d Cir. 2004) (quoting *Collier on Bankruptcy* §§ 510.01, 510.04 [1] (15th ed. 2004)).

[3] *See id.*

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the claims at issue here, "fall squarely within the intended scope of § 510(b)." Accordingly, this Court should hold that these claims are subordinated to the same priority as Tricida's common stock, which will not receive a distribution pursuant to the Plan (defined below).

Jurisdiction and Venue

2. This Court has subject matter jurisdiction to consider this matter pursuant to 28 U.S.C. §§ 157 and 1334. This is a core proceeding pursuant to 28 U.S.C. § 157(b)(2)(A), (E) and (O). Venue is proper before this Court pursuant to 28 U.S.C. §§ 1408 and 1409.

3. The Trustee consents to the entry of a final order or judgment in this matter by the Court if it is determined that absent consent the Court cannot enter final orders or judgments consistent with Article III of the U.S. Constitution.

4. The statutory predicate for the relief requested in this Motion is Section 510(b) of the Bankruptcy Code, 11 U.S.C. §§ 101, *et seq.* (the "Bankruptcy Code").

Parties

5. The Liquidating Trustee is the trustee for the Liquidating Trust. The Liquidating Trust was formed in accordance with the *Fifth Amended Chapter 11 Plan of Liquidation for Tricida, Inc.* (the "Plan"). The Liquidating Trustee has a principal place of business located at 606 Post Road E #624 Westport, CT 06880.

6. Lead Plaintiff is the lead plaintiff in the proposed class action lawsuit captioned *Pardi Individually and on Behalf of All Others Similarly Situated v. Tricida, Inc. and Gerrit Klaerner,* Case No. 4:21-cv-00076-HSG (the "District Court Action"), pending in the United States District Court for the Northern District of California. The Lead Plaintiff is a resident of Texas and an equity holder of debtor Tricida, Inc. ("Tricida" or the "Debtor").

7. Fiore is a resident of Texas and an equity holder of Tricida.

Factual Background

A. Tricida's Bankruptcy Proceeding.

8. On January 11, 2023 (the "Petition Date"), Tricida filed a voluntary petition for relief under chapter 11 of the Bankruptcy Code in this Court. The Debtor continued in possession of its property and continued to operate and maintain its businesses as a debtor in possession pursuant to sections 1107(a) and 1108 of the Bankruptcy Code from the Petition Date through June 12, 2023, the effective date of the Plan (the "Effective Date").

9. On May 23, 2023, the Court entered its order [Docket No. 515] confirming the Plan. The Liquidating Trust was formed in accordance with the Plan. The Liquidating Trustee became the trustee of the Liquidating Trust effective as of the Effective Date.

B. Claim No. 144 filed by Lead Plaintiff.

10. Lead Plaintiff filed his claim ("Claim No. 144) on March 8, 2023.[4] The asserted basis for Claim 144 is "Violations of Federal Securities Laws - see addendum".[5] Paragraph 3 of the addendum to Claim No. 144 states as follows:

> The Amended Complaint generally alleges that the Defendants engaged in a deceptive scheme and made false and misleading statements and omissions of material fact about the design and execution of certain clinical trials, which artificially inflated and/or maintained artificial inflation in the price of the Debtor's common stock during the Class Period in violation of Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §78(a); and United States Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.[6]

11. Lead Plaintiff attached a redacted copy of the Second Amended Complaint for Violations of the Federal Securities Laws in the District Court Action (the "Second Amended

[4] A copy of Claim No. 144 is attached hereto as **Exhibit A**.

[5] See Claim No. 144, Box 8.

[6] See addendum to Claim No. 144, ¶ 3.

Complaint") as Exhibit A to Claim No. 144. The Second Amended Complaint asserts two causes of action, Count I against defendants Tricida and Klaerner and Count II against Klaerner only. Count I asserts a claim "For Violations of Section 10(b) of the Exchange Act and Rule 10b-5". In Count I, Lead Plaintiff makes the following allegations:

- During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and concealed material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.[7]

- Defendants "[e]mployed devices, schemes, and artifices to defraud.[8]

- Defendants "[m]ade untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading".[9]

- Defendants "[e]ngaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Tricida securities during the Class Period".[10]

- As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the Class have suffered damages in connection with their respective purchases of Tricida common stock during the Class Period, because, in reliance on the integrity of the market, they paid artificially inflated prices for Tricida securities and experienced losses when the artificial inflation was released from Tricida securities as a result of the revelations and prices decline detailed herein. Plaintiffs and the Class would not have purchased Tricida securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.[11]

12. In the prayer for relief, Lead Plaintiff requests a judgment, among other things, "[a]warding all damages and other remedies available under the Securities Exchange Act in favor

[7] Second Amended Complaint, ¶ 210.
[8] Second Amended Complaint, ¶ 212.
[9] Second Amended Complaint, ¶ 213.
[10] Second Amended Complaint, ¶ 214.
[11] Second Amended Complaint, ¶ 216.

of Lead Plaintiff and all members of the Class against Defendants in an amount to be proven at trial, including interest thereon"[12]

C. Claim No. 146 filed by Fiore.

13. Fiore filed his claim ("Claim No. 146) on March 8, 2023.[13] The asserted basis for Claim 144 is "Violations of Federal Securities Laws - see addendum".[14] Claim No. 146 attaches and relies on the Second Amended Complaint.

Relief Requested and Basis Therefore

14. By this Motion, the Liquidating Trustee requests that this Court enter an order subordinating Claim Nos. 144 and 146 to the same priority as Tridica's common stock pursuant to Section 510(b) of the Bankruptcy Code, which provides as follows:

> For the purpose of distribution under this title, a claim arising from rescission of a purchase or sale of a security of the debtor or of an affiliate of the debtor, for damages arising from the purchase or sale of such a security, or for reimbursement or contribution allowed under section 502 on account of such a claim, shall be subordinated to all claims or interests that are senior to or equal the claim or interest represented by such security, except that if such security is common stock, such claim has the same priority as common stock.

11 U.S.C. § 510(b). "11 U.S.C. § 510(b) subordinates claims for damages arising from the purchase or sale of a security of the debtor to all claims and interests that are senior or equal to the claim or interest represented by such security. Where, as here, the security is common stock, the claim has the same priority as common stock."[15]

15. Congress enacted Section 510(b) to "prevent disaffected equity investors from recouping their investment losses in parity with general unsecured creditors in the event of

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[12] Second Amended Complaint, ¶ 225(b).

[13] A copy of Claim No. 146 is attached hereto as **Exhibit B**.

[14] See Claim No. 146, Box 8.

[15] *NMSBPCSLDHB, L.P. v. Integrated Telecom Express, Inc. (In re Integrated Telecom Express, Inc.*), 384 F.3d 108, 117, FN 2 (3d Cir. 2004) (citing *Collier on Bankruptcy* §§ 510.01, 510.04 [1] (15th ed. 2004)).

bankruptcy."[16] "[B]ecause claimants retained the right to participate in corporate profits if Telegroup succeeded, we believe that § 510(b) prevents them from using their breach of contract claim to recover the value of their equity investment in parity with general unsecured creditors. Were we to rule in claimants' favor in this case, we would allow stockholders in claimants' position to retain their stock and share in the corporation's profits if the corporation succeeds, and to recover a portion of their investment in parity with creditors if the corporation fails."[17]

16. A mandatory subordination claim under Bankruptcy Code Section 510(b) requires three elements: "first, the *claim involves a security;* second, that there was a purchase or sale of such security; and third that the damages which make up his claim arose out of that purchase or sale."[18] Each of these elements is satisfied here. Claim Nos. 144 and 146 both directly relate to the purchase of Tricida stock, satisfying the first two elements. The third element is satisfied because Claim Nos. 144 and 146 seek damages for Tricida's alleged violations of Section 10(b) of the Exchange Act and Rule 10b-5. Rule 10b-5 provides as follows:

> 240.10b-5 Employment of manipulative and deceptive devices.
>
> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,
>
> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,

[16] *In re Teleglobe, Inc.*, 281 F.3d 133, 142 (3d. Cir. 2002).
[17] *Id.*
[18] *In re NTP Marble, Inc.*, 491 B.R. 208, 2012 (Bankr. E.D. Pa. 2013) (citing *Liquidating Trust v. Wax (In re U.S. Wireless Corp.),* 384 B.R. 713, 717–718 (Bankr. D. Del. 2008)).

in connection with the purchase or sale of any security.[19]

17. The Second Amended Complaint is replete with allegations that Tricida made materially false and misleading statements and engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Tricida securities. Moreover, in paragraph 216 of the Second Amended Complaint, plaintiffs assert that, "[a]s a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the Class have suffered damages in connection with their respective purchases of Tricida common stock…." Shareholder claims, such as the claims asserted in the Second Amended Complaint, "alleging fraud in the issuance . . . fall squarely within the intended scope of § 510(b)."[20] If, as here, a damages claim would not exist but for the claimant's stock ownership, the claim is subordinated pursuant to Bankruptcy Code Section 510(b).[21]

18. In *Kaiser Group Intern., Inc.*,[22] Judge Walrath subordinated all claims included in a similar class action seeking damages for violations of securities laws, among other things. *Kaiser* involved the merger of ICT Spectrum Constructors, Inc. ("ICT") into an affiliate of Kaiser Group International, Inc. ("Kaiser") pursuant to an Agreement and Plan of Merger dated February 5, 1998 ("the Merger Agreement").[23] Pursuant to the Merger Agreement, the ICT shareholders received 1.5 million of restricted shares of Kaiser common stock. In addition, if the Kaiser stock did not have a value of $5.36 per share on March 1, 2001, the Merger Agreement required Kaiser to pay the difference in value by either issuing additional shares or paying cash. Further, although the Kaiser shares held by the ICT Shareholders were restricted (i.e., they could not be freely sold), the

[19] 17 CFR § 240.10b-5 (emphasis added).
[20] *In re Teleglobe, Inc.*, 281 F.3d 133, 143 (3d Cir. 2002).
[21] *Id.*
[22] *In re Kaiser Group Intern., Inc.,* 260 B.R. 684 (Bankr. D. Del. 2001).
[23] *Id.* at 685-86.

Merger Agreement provided that if the share price went above the $5.36 per share before March 1, 2001, the ICT shareholders had the right to require the Debtors to either buy the stock or arrange for the sale of the stock.[24]

19. A former ICT shareholder filed a proposed class action suit against Kaiser, its subsidiary, and certain Kaiser officers on March 24, 1999 alleging violation of the federal securities laws with respect to the ICT merger. The Debtors filed voluntary petitions under Chapter 11 of the Bankruptcy Code on June 9, 2000 and their Second Amended Plan of Reorganization was confirmed on December 5, 2000.[25]

20. The ICT Shareholders filed proofs of claim asserting damages arising from the ICT merger, including violations of securities laws, breach of contract, enforcement of the provisions of the Merger Agreement, and other claims arising under the complaint. The Debtors objected to the ICT Shareholders' claims asserting that all their claims must be subordinated under Bankruptcy Code Section 510(b).[26]

21. The ICT shareholders argued that the claims were not subject to subordination because the Merger Agreement required Kaiser to pay the difference between the Merger Value and the price of their stock in cash. The Court did not find this argument persuasive because "[t]he obligation to pay the Merger Value was an obligation undertaken by the Debtors in connection with the issuance of their stock and as a guarantee by the Debtors of the value of their stock. This is clearly a claim based on damages resulting from the sale or purchase of securities of the Debtors." The Court further found that, "while the ICT Shareholders attempt to recharacterize their claim in this Court to avoid the application of section 510(b), it is clear from the allegations in the

[24] *Id.* at 686.
[25] *Id.*
[26] *Id.*

… Complaint … that the basis of their claims is the allegation that the Debtors committed securities fraud and made material misrepresentations to the ICT Shareholders to induce them to enter into the Merger Agreement. Such allegations place their claims squarely within the purview of section 510(b).

22. Here, as in *Kaiser*, Claimants seek damages for Debtor's alleged securities fraud and material misrepresentation related to their purchase of Tricida common stock. Accordingly, as in *Kaiser*, this Court should hold that Claim Nos. 144 and 146 are subordinated pursuant to Section 510(b).

Conclusion

WHEREFORE, for the foregoing reasons, the Liquidating Trustee respectfully requests that this Honorable Court enter an order, substantially in the form attached as **Exhibit C**, subordinating Claim No. 144 and Claim No. 146 to the same priority as Debtor's common stock and granting to the Liquidating Trustee such other and further relief as is just and proper.

Date: August 11, 2023
Wilmington, DE

SULLIVAN · HAZELTINE · ALLINSON LLC

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Attorneys for Jackson Square Advisors as Liquidating Trustee for the Tricida Liquidating Trust

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	)	Chapter 11
	)	
Tricida, Inc., [1]	)	Case No. 23-10024 (JTD)
Debtor.	)	
	)	**Objection Deadline: September 1, 2023 at 4:00 p.m.**
	)	**Hearing Date: September 27, 2023 at 11:00 a.m.**

NOTICE OF MOTION

PLEASE TAKE NOTICE that on August 11, 2023 Jackson Square Advisors, solely in its capacity as liquidating trustee of the Tricida Liquidating Trust (the "Liquidating Trustee"), filed its *Motion of the Liquidating Trustee to Subordinate Claim No. 144 filed by Jeffrey Fiore, as Securities Lead Plaintiff for a Proposed Class of Plaintiffs, and Claim No. 146 filed by Jeffrey Fiore Individually Pursuant to 11 U.S.C § 510(b)* (the "Motion") with the United States Bankruptcy Court for the District of Delaware (the "Bankruptcy Court").

PLEASE TAKE FURTHER NOTICE that responses to the Motion, if any, must be filed on or before **September 1, 2023 at 4:00 p.m.** ("Response Deadline") with the United States Bankruptcy Court for the District of Delaware, Clerk's Office, 824 North Market Street, Third Floor, Wilmington, Delaware 19081 and served on the undersigned counsel to the Liquidating Trustee so as to be received on or before the Response Deadline.

PLEASE TAKE FURTHER NOTICE, that a hearing with respect to the Motion, if required, is scheduled before the Honorable John T. Dorsey at the Bankruptcy Court, 5th Floor, Courtroom 5, on **September 27, 2023 at 11:00 a.m.**

[1] The Debtor in this chapter 11 case, together with the last four digits of the Debtor's federal tax identification number, is Tricida, Inc. (2526). The Debtor's service address is 2108 N Street, Suite 4935, Sacramento, CA 95816.

PLEASE TAKE FURTHER NOTICE THAT IF NO OBJECTION OR OTHER RESPONSE TO THE MOTION IS TIMELY FILED IN ACCORDANCE WITH THE PROCEDURES SET FORTH ABOVE, THE BANKRUPTCY COURT MAY ENTER AN ORDER GRANTING THE RELIEF SOUGHT IN THE MOTION WITHOUT FURTHER NOTICE OR A HEARING.

Dated: August 11, 2023
Wilmington, Delaware

SULLIVAN • HAZELTINE • ALLINSON LLC

/s/ William A. Hazeltine

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Attorneys for Jackson Square Advisors

EXHIBIT A

Fill in this information to identify the case:

Debtor Tricida, Inc.

United States Bankruptcy Court for the: _____ District of Delaware (State)

Case number 23-10024

Official Form 410
Proof of Claim

04/22

Read the instructions before filling out this form. This form is for making a claim for payment in a bankruptcy case. Do not use this form to make a request for payment of an administrative expense. Make such a request according to 11 U.S.C. § 503.

Filers must leave out or redact information that is entitled to privacy on this form or on any attached documents. Attach redacted copies or any documents that support the claim, such as promissory notes, purchase orders, invoices, itemized statements of running accounts, contracts, judgments, mortgages, and security agreements. **Do not send original documents;** they may be destroyed after scanning. If the documents are not available, explain in an attachment.

A person who files a fraudulent claim could be fined up to $500,000, imprisoned for up to 5 years, or both. 18 U.S.C. §§ 152, 157, and 3571.

Fill in all the information about the claim as of the date the case was filed. That date is on the notice of bankruptcy (Form 309) **that you received.**

Part 1: Identify the Claim

1. **Who is the current creditor?**
   Securities Lead Plaintiff and Proposed Class - see addendum
   Name of the current creditor (the person or entity to be paid for this claim)
   Other names the creditor used with the debtor _____

2. **Has this claim been acquired from someone else?**
   ☑ No
   ☐ Yes. From whom? _____

3. **Where should notices and payments to the creditor be sent?**
   Federal Rule of Bankruptcy Procedure (FRBP) 2002(g)

Where should notices to the creditor be sent?	**Where should payments to the creditor be sent?** (if different)
See summary page	
Contact phone 973-597-2500	Contact phone _____
Contact email lsklar@lowenstein.com	Contact email _____

   Uniform claim identifier for electronic payments in chapter 13 (if you use one):
   _____

4. **Does this claim amend one already filed?**
   ☑ No
   ☐ Yes. Claim number on court claims registry (if known) _____ Filed on _____ MM / DD / YYYY

5. **Do you know if anyone else has filed a proof of claim for this claim?**
   ☑ No
   ☐ Yes. Who made the earlier filing? _____

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Part 2: Give Information About the Claim as of the Date the Case Was Filed

6. **Do you have any number you use to identify the debtor?**
   - ☑ No
   - ☐ Yes. Last 4 digits of the debtor's account or any number you use to identify the debtor: ___ ___ ___ ___

7. **How much is the claim?** $ unliquidated. **Does this amount include interest or other charges?**
   - ☐ No
   - ☐ Yes. Attach statement itemizing interest, fees, expenses, or other charges required by Bankruptcy Rule 3001(c)(2)(A).

8. **What is the basis of the claim?**
   Examples: Goods sold, money loaned, lease, services performed, personal injury or wrongful death, or credit card.
   Attach redacted copies of any documents supporting the claim required by Bankruptcy Rule 3001(c).
   Limit disclosing information that is entitled to privacy, such as health care information.

   Violations of Federal Securities Laws - see addendum

9. **Is all or part of the claim secured?**
   - ☑ No
   - ☐ Yes. The claim is secured by a lien on property.

   Nature or property:
   - ☐ Real estate: If the claim is secured by the debtor's principle residence, file a *Mortgage Proof of Claim Attachment* (Official Form 410-A) with this *Proof of Claim*.
   - ☐ Motor vehicle
   - ☐ Other. Describe: _____

   Basis for perfection: _____
   Attach redacted copies of documents, if any, that show evidence of perfection of a security interest (for example, a mortgage, lien, certificate of title, financing statement, or other document that shows the lien has been filed or recorded.)

   Value of property: $_____
   Amount of the claim that is secured: $_____
   Amount of the claim that is unsecured: $_____ (The sum of the secured and unsecured amount should match the amount in line 7.)

   Amount necessary to cure any default as of the date of the petition: $_____

   Annual Interest Rate (when case was filed)_____%
   - ☐ Fixed
   - ☐ Variable

10. **Is this claim based on a lease?**
    - ☑ No
    - ☐ Yes. **Amount necessary to cure any default as of the date of the petition.** $_____

11. **Is this claim subject to a right of setoff?**
    - ☑ No
    - ☐ Yes. Identify the property: _____

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12. **Is all or part of the claim entitled to priority under 11 U.S.C. § 507(a)?**

A claim may be partly priority and partly nonpriority. For example, in some categories, the law limits the amount entitled to priority.

☑ No

☐ Yes. *Check all that apply:*

	Amount entitled to priority
☐ Domestic support obligations (including alimony and child support) under 11 U.S.C. § 507(a)(1)(A) or (a)(1)(B).	$_____
☐ Up to $3,350* of deposits toward purchase, lease, or rental of property or services for personal, family, or household use. 11 U.S.C. § 507(a)(7).	$_____
☐ Wages, salaries, or commissions (up to $15,150*) earned within 180 days before the bankruptcy petition is filed or the debtor's business ends, whichever is earlier. 11 U.S.C. § 507(a)(4).	$_____
☐ Taxes or penalties owed to governmental units. 11 U.S.C. § 507(a)(8).	$_____
☐ Contributions to an employee benefit plan. 11 U.S.C. § 507(a)(5).	$_____
☐ Other. Specify subsection of 11 U.S.C. § 507(a)(__) that applies.	$_____

* Amounts are subject to adjustment on 4/01/25 and every 3 years after that for cases begun on or after the date of adjustment.

13. **Is all or part of the claim pursuant to 11 U.S.C. § 503(b)(9)?**

☑ No

☐ Yes. Indicate the amount of your claim arising from the value of any goods received by the debtor within 20 days before the date of commencement of the above case, in which the goods have been sold to the Debtor in the ordinary course of such Debtor's business. Attach documentation supporting such claim.

$_____

Part 3: Sign Below

The person completing this proof of claim must sign and date it. FRBP 9011(b).

If you file this claim electronically, FRBP 5005(a)(2) authorizes courts to establish local rules specifying what a signature is.

A person who files a fraudulent claim could be fined up to $500,000, imprisoned for up to 5 years, or both. 18 U.S.C. §§ 152, 157, and 3571.

Check the appropriate box:

☐ I am the creditor.

☑ I am the creditor's attorney or authorized agent.

☐ I am the trustee, or the debtor, or their authorized agent. Bankruptcy Rule 3004.

☐ I am a guarantor, surety, endorser, or other codebtor. Bankruptcy Rule 3005.

I understand that an authorized signature on this *Proof of Claim* serves as an acknowledgement that when calculating the amount of the claim, the creditor gave the debtor credit for any payments received toward the debt.

I have examined the information in this *Proof of Claim* and have reasonable belief that the information is true and correct.

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

Executed on date 03/08/2023
MM / DD / YYYY

/s/Lindsay Sklar
Signature

Print the name of the person who is completing and signing this claim:

Name: Lindsay Sklar
First name Middle name Last name

Title: Counsel

Company: Lowenstein Sandler LLP
Identify the corporate servicer as the company if the authorized agent is a servicer.

Address

Contact phone _____ Email _____

KCC ePOC Electronic Claim Filing Summary

For phone assistance: Domestic 866-476-0898 | International 001-310-823-9000

Debtor:
23-10024 - Tricida, Inc.
District:
District of Delaware

Creditor:
Securities Lead Plaintiff and Proposed Class - see addendum
Lowenstein Sandler LLP
Attn: Michael Etkin, Andrew Behlmann, Lindsay Skla
One Lowenstein Drive
Roseland, New Jersey, 07068
USA
Phone:
973-597-2500
Phone 2:
Fax:
973-597-2400
Email:
lsklar@lowenstein.com

Has Supporting Documentation:
Yes, supporting documentation successfully uploaded
Related Document Statement:

Has Related Claim:
No
Related Claim Filed By:

Filing Party:
Authorized agent

Other Names Used with Debtor:

Amends Claim:
No
Acquired Claim:
No

Basis of Claim:
Violations of Federal Securities Laws - see addendum

Last 4 Digits:
No

Uniform Claim Identifier:

Total Amount of Claim:
unliquidated

Includes Interest or Charges:
None

Has Priority Claim:
No

Priority Under:

Has Secured Claim:
No
Amount of 503(b)(9):
No
Based on Lease:
No
Subject to Right of Setoff:
No

Nature of Secured Amount:
Value of Property:
Annual Interest Rate:
Arrearage Amount:
Basis for Perfection:
Amount Unsecured:

Submitted By:
Lindsay Sklar on 08-Mar-2023 3:05:08 p.m. Eastern Time
Title:
Counsel
Company:
Lowenstein Sandler LLP

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	Chapter 11
TRICIDA, INC.,[1]	Case No. 23-10024 (JTD)
Debtor.	(Jointly Administered)

ADDENDUM TO CLASS PROOF OF CLAIM

1. This class proof of claim is submitted against Tricida, Inc. (the "Debtor") by the court-appointed lead plaintiff ("Lead Plaintiff") in the securities class action styled as *Michael Pardi v. Tricida, Inc. and Gerrit Klaerner, Case No. 4:21-cv-00076-HSG* (the "Securities Litigation"), pending in the United States District Court for the Northern District of California, Oakland Division (the "District Court"), for himself and on behalf of the proposed class in the Securities Litigation (the "Proposed Class").

2. On July 29, 2022, the District Court upheld in part a complaint against the Debtor and its CEO, Gerrit Klaerner (collectively, "Defendants") for violations of Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §78(a); and United States Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder. Following this ruling, and after discovery commenced, Lead Plaintiff obtained documents from the United States Food and Drug Administration and used that evidence to file the *Second Amended Complaint for Violations of the Federal Securities Laws* on December 15, 2022 (the "Amended Complaint") [Securities Litigation Docket No. 115] against Defendants. The Proposed Class is currently defined in the Amended Complaint as all investors, other than Defendants, who

[1] The Debtor in this chapter 11 case, together with the last four digits of the Debtor's federal tax identification number, is Tricida, Inc. (2526). The Debtor's service address is 7000 Shoreline Court, Suite 201, South San Francisco, CA 94080.

purchased or otherwise acquired Tricida, Inc. common stock between June 28, 2018 through February 25, 2021, inclusive (the "Class Period").[2] A copy of the Amended Complaint is attached hereto as Exhibit A and incorporated herein by reference. All references herein to the Amended Complaint are qualified in their entirety by the Amended Complaint itself. The Amended Complaint re-asserts the theory already upheld and adds additional evidence of wrongdoing by Defendants on behalf of the Proposed Class.

3. The Amended Complaint generally alleges that the Defendants engaged in a deceptive scheme and made false and misleading statements and omissions of material fact about the design and execution of certain clinical trials, which artificially inflated and/or maintained artificial inflation in the price of the Debtor's common stock during the Class Period in violation of Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §78(a); and United States Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

4. By operation of the automatic stay pursuant to 11 U.S.C. § 362, the Securities Litigation is stayed solely with respect to the Debtor. Accordingly, on January 24, 2023, Lead Plaintiff filed a motion to voluntarily dismiss the Debtor as a defendant without prejudice.

5. As of January 11, 2023 (the "Petition Date"), and continuing up to and including the present, the Debtor was and remains liable to Lead Plaintiff and the Proposed Class for damages in an amount not yet determined, plus interest, costs, and attorneys' fees as allowed (the "Class Claim"). The allegations in the Amended Complaint, as may be further amended from time to time, form the basis of the Class Claim against the Debtor. The basis of the Class Claim against the Debtor (as well as the claims of Lead Plaintiff and the Proposed Class against Mr.

[2] Lead Plaintiff reserves the right to amend the definition of the Proposed Class, including but not limited to the Class Period .

Klaerner and any other defendants to be named in the Securities Litigation) is damages resulting from violations of the federal securities laws by the Defendants in connection with the purchase or other acquisition by Lead Plaintiff and the Proposed Class of certain securities issued by or on behalf of the Debtor.[3]

6. Lead Plaintiff files this proof of claim on behalf of himself and the Proposed Class and its members, individually and/or as a group, with a reservation of rights to identify additional members of the Proposed Class in the future.

7. The Class Claim is not founded upon a specific writing, although certain documents, too voluminous and burdensome to annex hereto, which upon information and belief, relate to the Debtor's violations of the federal securities laws from which the Class Claim arises, and which include, but are not limited to, documents filed with the United States Securities and Exchange Commission, are available. In addition, certain of these documents, as well as other documents, may become available through discovery with respect to the Class Claim.

8. No payments have been made on account of the Class Claim.

9. The Class Claim is not subject to any setoff or counterclaim.

10. No security interest is held for the Class Claim.

11. The Class Claim is asserted in addition to, and not in lieu of, all other claims that Lead Plaintiff, the Proposed Class, and/or any individual members of the Proposed Class may have against the Debtor, its affiliates, Mr. Klaerner, and any other defendants to be named in the Securities Litigation.

12. Lead Plaintiff reserves all rights (including but not limited to arguments, counterarguments, and defenses) in connection with the Securities Litigation. Lead Plaintiff

[3] Lead Plaintiff reserves the right to amend the description of the Class Claim from time to time, including but not limited to asserting additional bases for the Class Claim, in connection with any further amendment of the Amended Complaint and/or the discovery of additional information relevant to the Class Claim.

further reserves all rights with respect to the Class Claim and this proof of claim, including but not limited to the right to amend and/or supplement this proof of claim from time to time and/or move to withdraw the bankruptcy reference with respect to any claim, cause of action, issue, or proceeding, whether or not encompassed in the Class Claim or asserted in this proof of claim.

13. This proof of claim and any subsequent appearance, pleading, claim, or suit made or filed by Lead Plaintiff, either individually or for the Proposed Class or any member thereof, shall not be deemed to:

- constitute a submission by Lead Plaintiff, either individually or for the Proposed Class or any member thereof, to the jurisdiction of the Bankruptcy Court;
- constitute consent by Lead Plaintiff, either individually or for the Proposed Class or any member thereof, to entry by the Bankruptcy Court of any final order in any non-core proceeding, **which consent is hereby withheld unless expressly granted in the future with respect to a specific issue, matter, or proceeding**;
- waive any substantive or procedural rights of Lead Plaintiff or the Proposed Class or any member thereof, including but not limited to (a) the right to challenge the constitutional authority of the Bankruptcy Court to enter a final order or judgment, or any order having the effect of a final order or judgment, on any matter; (b) the right to have final orders in non-core matters entered only after *de novo* review by a United States District Court; (c) the right to trial by jury in any proceedings so triable herein, in the Securities Litigation, or in any other case, controversy, or proceeding related to or arising from the Debtor, this chapter 11 bankruptcy case, any related proceedings, or the Securities Litigation; (d) the right to have the applicable United States District Court withdraw the reference

in any matter subject to mandatory or discretionary withdrawal; (e) the right to request that the Bankruptcy Court abstain from hearing the merits of the Class Claim pursuant to 28 U.S.C. § 1334(c); (f) the right to assert any and all claims or rights against others jointly or severally liable for the sums claimed herein; or (g) all other rights, claims, actions, arguments, counterarguments, defenses, setoffs, or recoupments to which Lead Plaintiff or the Proposed Class or any member thereof are or may be entitled under agreements, at law, in equity, or otherwise, all of which rights, claims, actions, arguments, counterarguments, defenses, setoffs, and recoupments are expressly reserved, nor shall this class proof of claim be deemed to constitute consent to electronic service of any pleading or papers for which mailed or personal service is required under any applicable law, rule, regulation, or order.

EXHIBIT A
Amended Complaint

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

MICHAEL PARDI, *Individually and on Behalf of All Others Similarly Situated,* Plaintiff, v. TRICIDA, INC. and GERRITT KLAERNER, Defendants.	Case No. 4:21-cv-00076-HSG **SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **[REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED]** **Class Action** ***Demand for Jury Trial***

1. Lead Plaintiff alleges the following based upon the investigation conducted by and through his attorneys, Block & Leviton LLP. This investigation included, but was not limited to review and analysis of (i) Tricida's public filings with the U.S. Securities and Exchange Commission ("SEC"), (ii) transcripts of Tricida's public conference calls, (iii) Tricida's press releases, (iv) independent media reports regarding Tricida, (v) securities analysts' reports and advisories about the Company, (vi) other public statements issued by the Company, (vii) media reports about the Company, and (viii) documents produced during pre-trial discovery by the United States Food and Drug Administration ("FDA"). Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION

2. This is a securities class action alleging violations of §§10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5, 17 C.F.R. § 240.10b-5, as promulgated thereunder, against Defendants Tricida, Inc. ("Tricida" or the "Company") and Gerrit Klaerner, Ph.D. who founded Tricida and has served as Tricida's Chief Executive Officer and President since August 2013 and is a member of its Board of Directors.

3. This action is brought on behalf of all investors who purchased Tricida common stock during the period June 28, 2018 through February 25, 2021 (the "Class Period").

4. The case concerns materially false and misleading statements and omissions of material facts about Tricida's attempts to gain approval from the FDA for its lead investigational drug candidate, veverimer (TRC101), "a non-absorbed, orally administered polymer designed to treat metabolic acidosis by binding and removing acid from the gastrointestinal tract." Veverimer is intended to slow the progression of chronic kidney disease ("CKD") through the treatment of metabolic acidosis.

5. Tricida conducted a single Phase 3 study for veverimer and sought approval under the FDA's Accelerated Drug Application ("ADA") program. To obtain approval under the ADA, a pharmaceutical company also must conduct a valid post-marketing trial.

6. In May 2018, before the Class Period begins, Tricida completed its phase 3 study for veverimer ("TRCA-301"). In a press release dated June 5, 2018, Tricida announced that TRCA-301, "was conducted at 47 sites in the United States and Europe," and "met both its primary and secondary endpoints in a statistically significant manner."

7. Based on the purported strength of these trial results, Tricida went public on June 28, 2018, selling 13,455,000 million shares of its common stock to the class at $19 per share (including the exercise of options by the underwriters of the offering) and raising $255.6 million. Shares began to trade on Nasdaq on June 28, 2018. The offering registration statement, and its accompanying prospectus (the "2018 Prospectus"), misrepresented material facts and omitted to reveal material facts necessary to make the statements that were made therein, not materially misleading.

8. In the 2018 Prospectus, Defendants misrepresented that *"[b]ased on feedback from the FDA*, we believe that the data from the TRCA-101, TRCA 301 and TRCA 301E trials will provide sufficient evidence of clinical safety and efficacy to support the submission and review of an NDA for TRC101 pursuant to the Accelerated Approval Program." 2018 Prospectus at 4. (Emphasis added.)

9. The FDA, however, provided Defendants with specific feedback making the claim that the trials would "provide sufficient evidence of clinical safety and efficacy" materially false and misleading.

[redacted]

[redacted]

21. [redacted] Tricida informed its investors in its 2019 Form 10-K, filed with the SEC on March 2, 2020, that "[w]e believe that the

data from the TRCA-101, TRCA-301 and TRCA 301E clinical trials *will provide sufficient clinical evidence of safety and efficacy to support the approval of our NDA* for veverimer pursuant to the Accelerated Approval Program." (Emphasis added).

22. This statement was materially false and misleading when made. [redacted] Defendants had no basis to claim a belief that the clinical trials provided "sufficient clinical evidence of safety and efficacy to support the approval of our NDA."

[redacted]

[redacted]

26. But on May 7, 2020, during Tricida's 1Q20 earnings call with analysts, Klaerner misrepresented [redacted]:

> In our Day 74 letter, the FDA indicated that they plan to hold an advisory committee meeting or AdCom to discuss the application. *In our late-cycle*

> *meeting with the FDA held in May 2020, the FDA indicated it currently* does *not plan to hold an AdCom to discuss veverimer due in part to the logistical challenges posed by COVID-19. In our late-cycle meeting with FDA, we took the opportunity to address outstanding review issues.* We presented our data and rationale as to why *we think we very much satisfied the requirements for initial approval under the Accelerated Approval Program including the magnitude and durability of the treatment effect on the surrogate markup serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials.*
>
> Under the initial approval, we have to ensure that US patients who would be prescribed veverimer get clinically significant benefit that outweighs the risk of treatment. *Overall, while the FDA continues its review, we remain confident that our submission meets the standard for approval through the Accelerated Approval Program.*

(emphasis added). [redacted] Klaerner blamed the cancellation of the AdCom meeting on COVID-19. This was false. Plus, by purporting to reveal discussions with the FDA from the May 2020 late-cycle meeting, [redacted] Klaerner misleadingly inflated veverimer's likelihood of FDA approval to investors.

27. Tricida would later have more to say about the late cycle meeting (in its Second Quarter 10-Q filed with the Securities and Exchange Commission ("SEC") on August 6, 2020):

> In our late cycle meeting with the FDA, held in May 2020, we addressed two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population.[1]

But Tricida did not reveal the entire truth as to the reasons underlying why the FDA found the data supporting TRCA-301 to be insufficient until it revealed its receipt of the ADL on February 25, 2021.

28. On July 15, 2020, at 5 pm, after the close of trading, Tricida issued a press release revealing that it had received a notification from the FDA "stating that, as part of its ongoing review of the Company's [NDA], the FDA has identified deficiencies that preclude discussion of

[1] Tricida also stated for the first time that it anticipated receiving a Complete Response Letter ("CRL") for its veverimer NDA, but misleadingly feigned ignorance as to the reasons why.

labeling and postmarketing requirements/commitments at this time…. The notification does not specify the deficiencies identified by the FDA." While the notification itself may not have specified the "deficiencies identified by the FDA," Tricida already knew of those deficiencies from its May 2020 meeting and continued to conceal them from investors. Tricida's stock price plunged on July 16, 2020, on this news, falling 40% from its closing price of $26.20 per share on July 15, 2020, to close at $15.64 on July 16, 2020, wiping out over $530 million in market capitalization.

29. Tricida issued a press release on August 24, 2020, at 8:30 am, prior to the opening of trading, that it received a Complete Response Letter ("CRL") from the FDA for its NDA for veverimer. Tricida disclosed, among other things, that "According to the CRL, the FDA is seeking additional data beyond the TRCA-301 and TRCA-301E trials regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and the applicability of the treatment effect to the U.S. population. FDA also expressed concern as to whether the demonstrated effect size would be reasonably likely to predict clinical benefit." Tricida's stock price fell by $3.13 per share, or 24% on this news, wiping out approximately $157 million in market capitalization.

30. On October 29, 2020, before markets opened, Tricida announced that during an End-of-Review Type A conference held October 20, 2020, with the FDA's Division of Cardiology and Nephrology—which had issued the CRL on August 21, 2020, denying Tricida's veverimer NDA—the FDA told Tricida that it was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would therefore "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program." But because Tricida could not provide this interim information from the VALOR-CKD trial "without compromising the integrity of the ongoing trial," additional trials would be required to gather this information. In other words, the FDA rejected the veverimer NDA because the single phase 3 trial's surrogate endpoint was not an adequate stand-in for clinical efficacy. The same press release disclosed that Tricida was "significantly reducing its headcount from 152 to 59 people and will discuss its commitments with vendors and contract service providers to potentially provide additional financial flexibility."

31. In response to this news, Tricida's stock price fell 47% from its closing price of $8.27 per share on October 28, 2020, to close at $4.37 per share on October 29, 2020, wiping out nearly another $200 million in market capitalization.

32. Tricida issued a press release on December 8, 2020, sixteen minutes before markets closed for the day, announcing that the Company had failed to "come to a resolution with the Division of Cardiology and Nephrology on the resubmission of our NDA during our Type A meeting," submitted a Formal Dispute Resolution Request arguing that the TRCA-301 trial results are reasonably likely to predict clinical benefit, and revised the protocol for the VALOR-CKD trial. On this news, Tricida's stock price fell 17.73%, from a close of $8.12 per share on December 8, 2020, to close at $6.68 per share on December 9, 2020, wiping out yet another $72 million in market capitalization

33. Twenty-five minutes before markets closed on February 25, 2021, Tricida announced that it had received an ADL from the FDA. The ADL concluded (1) the "extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression," (2) "the confirmatory trial, VALOR-CKD, is underpowered," (3) the trial results were "strongly influenced by a single site," and (4) "the majority of sites for the TRCA-301/TRCA-301E trial" were in Eastern Europe, "where differences in patient management … might affect the treatment response to veverimer," rendering questionable "the applicability to a U.S. patient population." This was the first time Tricida revealed to investors that the trial results were "strongly influenced by a single site" and that the "majority of sites" for the trials were in Eastern Europe. Tricida's stock price fell 30.57% in response to these revelations, from a closing price of $7.36 per share on February 25, 2021, to $5.11 per share a close on February 26, 2021, wiping out $93 million more in market capitalization.

34. Lead Plaintiff, Jeffrey M. Fiore, and all other investors purchased Tricida common stock at artificially inflated prices and were damaged as the truth was revealed and the artificial inflation was eliminated.

JURISDICTION AND VENUE

35. This Complaint asserts claims under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b-5").

36. This Court has jurisdiction over the subject matter of this action under Section 27 of the Exchange act, 15 U.S.C. § 78aa and 28 U.S.C. §§ 1331 and 1337.

37. Venue is proper in this District under Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b), (c), and (d). Many of the acts and omissions that constitute the alleged violations of law, including the dissemination to the public of untrue statements of material facts, occurred in this District.

38. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of national securities exchanges.

PARTIES

39. Lead Plaintiff Jeffrey M. Fiore, a resident of Texas, purchased Tricida common stock during the Class Period on the Nasdaq Global Select Market and was damaged thereby. *See* ECF No. 12-2, Ex. B.

40. Defendant Tricida is a Delaware corporation with principal executive offices located at 7000 Shoreline Court, Suite 201, South San Francisco, California 94080. Tricida common stock trades in an efficient market on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "TCDA." Since its founding in 2013, the Company has incurred significant operation losses and had yet to develop any drug that the FDA approved for marketing and sales in the United States. Tricida is a control person of Gerrit Klaerner within the meaning of § 20(a) of the Exchange Act.

41. Defendant Gerrit Klaerner, Ph.D. founded Tricida and has served as Tricida's Chief Executive Officer and President since August 2013. He has also held a seat on Tricida's board of directors since July 2013. Previously, Klaerner founded Relypsa, Inc., serving as President and

Director from October 2007 until June 2013. Before that, Klaener co-founded Ilypsa, Inc., serving as its Director of Technology Assessment and Business Development from January 2003 until December 2006, and as its Chief Business Officer and Senior Vice President from December 2006 until July 2007. Before Ilypsa, Klaerner was employed at Symyx Technologies, Inc. as a Staff Scientist, Senior Staff Scientist, and Director Business Development. Klaerner attended meetings with and inspections by the FDA, including the May 6. 2015 meeting, the November 30, 2016 meeting, the February 9, 2017 meeting, the July 26, 2017 meeting, the March 6, 2018 meeting, the June 3, 2019 meeting, the January 27, 2020 meeting, and the May 1, 2020 meeting. Additionally, the Establishment Inspection Report for the inspection of Tricida's South San Francisco facility from December 9-17, 2019, reports that the FDA inspector met with Klaerner before the facility inspection and afterwards to debrief the results.

42. Prior to and during the Class Period, Klaerner was responsible for complying with the Company's Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics deemed Klaerner, as Chief Executive Officer, one of the three "sole authorized spokepersons for the Company." Klaerner made or had authority over the content and dissemination of the false and misleading statements and omissions set forth herein and is liable for those false statements and omissions. Klaerner is also a control person of Tricida within the meaning of § 20(a) of the Exchange Act.

BACKGROUND

43. A healthy kidney filters toxins and other harmful substances, including acid, from the blood. Patients suffering from chronic kidney disease ("CKD"), however, have a compromised ability to excrete acid via their kidneys. Consequently, CKD patients can develop metabolic acidosis – an excessive buildup of acid in body fluids. If not treated, Metabolic acidosis can result in progression of CKD, muscle breakdown, the development or exacerbation of bone disease, and death.

44. Metabolic acidosis in patients with CKD is often treated in the U.S. with oral alkali supplements, such as oral antacids. However, alkali supplements reduce acid levels at the cost of raising sodium levels in the body, which can in turn worsen conditions that commonly accompany

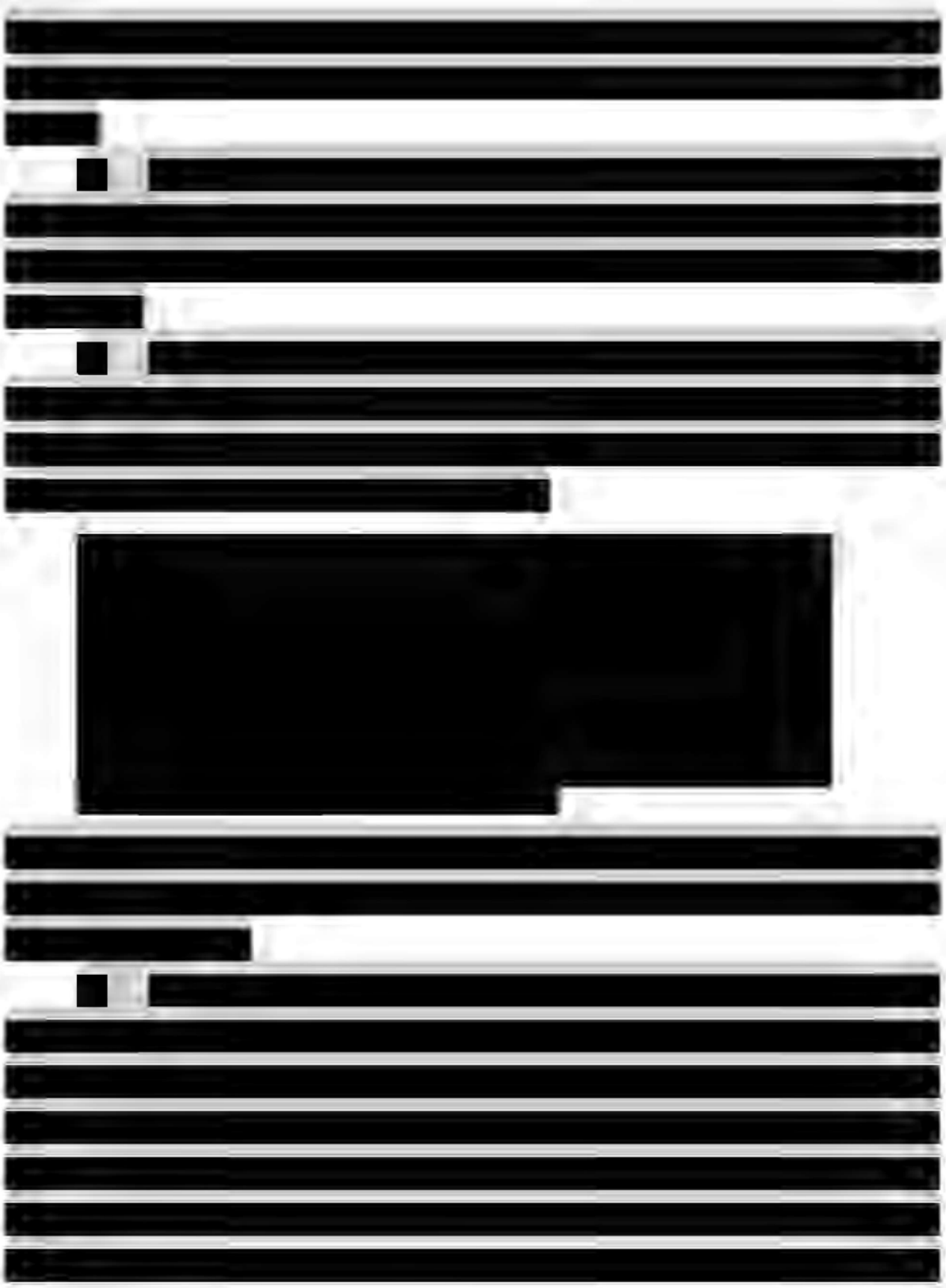
CKD, such as hypertension and heart failure. Consequently, alkali supplements typically cannot be used in patients with anything more than mild cases of metabolic acidosis, and there exists an unmet need for safe and effective treatments for metabolic acidosis in patients with CKD.

45. Tricida, founded in 2013, is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of non-absorbed therapies. Its lead investigational drug candidate is veverimer (TRC101), "a non-absorbed, orally administered polymer designed to treat metabolic acidosis by binding and removing acid from the gastrointestinal tract." Veverimer is intended to bind with hydrochloric acid in the gastrointestinal tract, thereby purporting to slow the progression of CKD through the treatment of metabolic acidosis.

46. Tricida planned to submit its NDA for veverimer to the FDA for review through the Agency's ADA. Under the ADA, if the Phase 3 program demonstrates clinical efficacy by achieving a predetermined surrogate endpoint, actual clinical efficacy (*e.g.* reduced progression of CKD) must thereafter be demonstrated through a confirmatory postmarketing trial. Tricida sought to use blood serum bicarbonate ("SBC") levels as a surrogate endpoint.

TRICIDA'S INTERACTIONS WITH THE FDA

[redacted]



[redacted]

[redacted]

[redacted]

62. In May 2018, Tricida completed the single veverimer Phase 3 trial, TRCA-301. In announcing the trial's results, Tricida described TRCA-301 as a "multicenter, randomized, double-blind, placebo controlled" clinical trial. The Company announced on June 5, 2018, that TRCA-301, which "was conducted at 47 sites in the United States and Europe," "met both its primary and secondary endpoints in a statistically significant manner" and that 196 of the 217 CKD patients from the Phase 3 TRCA-301 trial agreed to continue their participation in a 40-week blinded extension trial (TRCA-301E).

63. Tricida knew that the majority of trial sites were in Eastern Europe and that a single site was almost entirely responsible for the trial's favorable results. [redacted]

[redacted]

65. Nonetheless, capitalizing on what it presented as positive Phase 3 trial results, Tricida made an initial public offering ("IPO") of stock on June 28, 2018 and sold approximately $255 million in common stock to the class. The 2018 Prospectus touted the success of the TRCA-301 trial and represented that "[b]ased on feedback from the FDA, we believe that the data from the TRCA-101, TRCA-301, and TRCA-301E trials will provide sufficient evidence of clinical safety and efficacy to support the submission and review of an NDA for TRC101 pursuant to the [ADA]."

66. During an earnings call on March 28, 2019, Klaerner reported that Tricida had the results of TRCA-301's extension trial, TRCA-301E, which continued on with willing participants for 40 additional weeks after TRCA-301's 12-week run. Klaerner reported that the combined results of the TRCA-301/TRCA-301E trial "far exceeded our expectations": Not only did the extension trial "me[e]t its primary and all secondary endpoints," but "we have observed evidence of clinical benefit in TRC101-treated subjects, including reduced all-cause mortality, slowing of CKD progression and improved physical function." Klaerner shared that "we feel good about what we've learned in the 301E study regarding safety and efficacy, increasing our confidence for a successful VALOR-CKD trial."

67. Tricida and Klaerner repeated the same statements about the success of the Phase 3 pivotal trial, its extension, and the design of the confirmatory postmarketing trial (without mentioning any of their known critical shortcomings) in each and every Tricida SEC filing and quarterly earnings call through May 2020.

68. During the Q4 2018 earnings call on March 28, 2019, Chief Financial Officer Geoffrey M. Parker reported that Tricida's cash, cash equivalents, and investments totaled $243.4 at the end of 2018, which, in conjunction with a recently amended debt facility, would only allow the Company to fund its "anticipated operating expenses and capital expenditure requirements into 2021," i.e. "the initial commercial launch period for TRC101." The Company had raised

approximately $255 million in its initial public offering in June 2018, so without the funds raised in the offering, at that point in time, Tricida, would have been out of cash. Tricida needed additional money to fund anything other than a flawless accelerated approval of veverimer, and even then, there was not enough cash to fully commercialize the drug. Based on the publicly-presented prospects for FDA approval for veverimer, Tricida sold 6.44 million shares of common stock, at $36 per share, for over $231 million in a secondary stock offering completed on April 8, 2019.

[redacted]

71. On September 4, 2019, Tricida announced that it had submitted the veverimer NDA through the ADA in late August 2019. And on November 14, 2019, Tricida announced that the FDA had accepted its NDA for review under the ADA and assigned a Prescription Drug User Fee Act ("PDUFA") date of August 22, 2020. Tricida also mentioned that enrollment in the VALOR-CKD trial was estimated to be completed in mid-2020.

72. [redacted]

[redacted]

[redacted]

77. The late-cycle meeting itself took place on May 1, 2020. [redacted]

78. On July 14, 2020, Tricida received a letter [redacted]

TRICIDA AND KLAERNER REVEAL THE FDA'S CONCERNS PIECEMEAL

79. Tricida announced in a press release on, July 15, 2020, that it had received a notification from the FDA "stating that, as part of its ogoing review of the Company's [NDA], the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time…. The notification does not specify the deficiencies identified by the FDA." In response to this news, on unusually heavy trading activity, Tricida's stock price dropped sharply in one day, falling $10.56 per share in response to the news to close at $15.64 per share on July 16, 2020.

80. Although the notification may not have specified the deficiencies, Tricida and Klaerner knew the deficiencies the FDA had been raising for years. Indeed, they—better than anyone—knew the shortcomings of the veverimer trials. The second quarter 2020 Form 10-Q, filed August 6, 2020, finally disclosed some of the deficiencies:

> In our late cycle meeting with the FDA, held in May 2020, we addressed two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population.

In the same 10-Q, the Company finally conceded that "we are likely to receive … a Complete Response Letter, or CRL."

81. During an August 5, 2020, earnings call, an analyst demonstrated how even experts in the market had been misled into believing that Tricida had secured the FDA's cooperation, asking Klaerner to "remind us of the process that you went through to get the FDA to sign off on the design of the pivotal study and in particular, the serum bicarbonate primary endpoint. Was there any disagreement between you and the FDA in the design? Or are you both on the same page?" Klaerner offered a carefully worded response, stating the Company had reached agreement with the FDA (1) "that we are treating a serious disease, that there is an unmet medical need and that we have a surrogate that's likely going to translate to clinical benefit," and (2) on "a quantitative understanding … of how the surrogate really impacts … the progression of kidney disease." Based on those agreements, said Klaerner, Tricida designed the TRCA-301/TRCA-301E and VALOR-CKD trials.

82. On August 24, 2020, Tricida announced that it had received the anticipated CRL and revealed that the FDA's concerns were, in fact, the very issues the FDA had raised in advance of the late cycle meeting in May 2020 (and which Tricida had always known, but never disclosed to the market). Klaerner was quoted as saying "we are pleased that the FDA has provided helpful, specific comments and indicated their willingness to continue to work with us to pursue approval of veverimer." The Company also said it would request a Type A meeting with the FDA to discuss next steps.

83. The contents of the CRL were not disclosed to the market. [redacted]

85. On September 21, 2020, Tricida formally requested a Type A meeting with the FDA. [redacted]

86. On October 29, 2020, Tricida provided an update to investors on the Type A meeting. Tricida proposed conducting an interim analysis of data from about 500 patients in the VALOR-CKD trial, hoping that it would allow the Company to resubmit its NDA "within a matter of months," but the FDA rejected the proposal. "Based on feedback during the Type A meeting,"

Tricida revealed that it "now believes the FDA will also require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program and that the FDA is unlikely to rely solely on serum bicarbonate data for determination of efficacy."

87. During an analyst call the same day, Klaerner acknowledged for the first time that the TRCA-301/TRCA-301E trials failed to enroll enough subjects who were representative of the U.S. patient population. Describing future enrollment in the VALOR-CKD trial, Klaerner said, "We are focusing on U.S. and Western Europe and Canada to get more patients from those regions, *even though we think that patients are pretty much the same all over the world*, but it does make sense to add in a few more from those more U.S.-like countries. And FDA asked us to do that." (Emphasis added).

88. The stock price took another hit on this news, falling from a closing price of $8.27 per share on October 28, 2020, to close at $4.37 per share on October 29, 2020.

89. On December 8, 2020, Tricida announced that it had revised the protocol for its VALOR-CKD trial, switching from "an adaptive design" with "an unblinded interim analysis for sample size re-estimation" to "a group sequential design, no interim analysis for sample size adjustment, and unblinded interim analyses for early stopping for efficacy after 150 primary endpoint events … and 250 primary endpoint events … have accrued." Despite having repeatedly stated its commitment to fully enrolling or nearly fully enrolling the VALOR-CKD trial prior to NDA submission, Tricida revised the expected date by which enrollment would be completed to the end of 2022.

90. Tricida submitted a Formal Dispute Resolution Request just a few days earlier, on December 3, 2020, in a final attempt to convince the FDA that the magnitude and durability of serum bicarbonate change seen in the TRCA-301/TRCA-301E trial was reasonably likely to predict clinical benefit in the treatment of CKD.

91. On February 17, 2021, Tricida received an Appeal Denied Letter ("ADL") from the FDA's Office of New Drugs ("OND"). OND cited to its prior communications with Tricida in

explaining that it had consistently maintained that the treatment effect on serum bicarbonate would have to be of sufficient magnitude to justify approval:

> In addition to the limitations of Study TRCA-301/-301E leading to the determination that there was not substantial evidence of effectiveness based upon this single trial, the Division also concluded that the extent of effect on SBC observed was not "reasonably likely" to predict benefit on CKD progression. In earlier meetings you had with the Division, the Division expressed skepticism that SBC was an acceptable surrogate for delay of CKD progression. For example, the Division commented that "...we do not agree that the submitted data are sufficient to support the use of serum bicarbonate concentrations as a surrogate endpoint for a treatment effect on renal, bone, and/or muscle function-related outcomes in the proposed population." (Meeting Minutes 12/23/2016). In a subsequent meeting, the Division ultimately did agree that SBC may be a reasonably likely surrogate ***but noted that "a key issue is whether the magnitude of the treatment effect on serum bicarbonate....is sufficient to provide confidence that the treatment will have the anticipated benefit..."***. (Meeting Minutes, 3/9/17). The Division went on to point out that the way to assess this was to assure that the confirmatory trial was powered to see the anticipated effect size on CKD progression.
>
> * * *
>
> You note that the 5.5 mEq/L increase relative to placebo predicts a 32% relative risk reduction in the CKD composite. You then state that "the Division's suggestion that any benefit short of this would be seen as unacceptably modest is not defensible." (Page 27, FDRR letter). ***As I have already noted, this misrepresents the concern expressed in the CR letter—that the relatively small increase in SBC with TRC101 may not provide a discernible reduction in CKD progression. . . . this perspective is entirely consistent with prior advice from the Division***—as I noted already. That is, the increment in SBC with TRC101 in Study TRCA-301/-301E does not meet the "test" advised by the Division—that the size of the increase in SBC should be anticipated to translate to a reduction in the renal composite endpoint for which the confirmatory study is powered (meeting minutes 3/9/17, quoted above).

(Emphasis added).

92. On February 25, 2021, Tricida disclosed its receipt of the ADL and shared the basis for the OND's rejection of the veverimer NDA:

> In the ADL, the OND acknowledged that the TRCA-301/TRCA-301E trial met its serum bicarbonate endpoints with statistical significance but concluded that the extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a

> discernible reduction in CKD progression. The OND also concluded that the confirmatory trial, VALOR CKD, is underpowered to detect the effect size (13%) predicted by the original Tangri model (also known as the Predictive MA Model) based upon the placebo-subtracted mean treatment effect observed in the TRCA-301/TRCA-301E trial.
>
> The OND also provided feedback on other concerns that are particularly relevant in an NDA supported by a single registrational trial. The OND noted concerns around the trial results being strongly influenced by a single site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population.

93. Tricida's stock price took another hit as investors responded to this news, falling from a close of $7.36 per share on February 25, 2021, to close at $5.11 per share on February 26, 2021.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

Pre-Class Period Statements

94. On June 5, 2018, Tricida issued a press release titled "Tricida Announces Positive Pivotal Phase 3 Clinical Trial Results for TRC101 in CKD Patients with Metabolic Acidosis." The press release stated, in pertinent part,

> Tricida, Inc., a late-stage pharmaceutical company, announced results from *its pivotal Phase 3 double-blind, randomized, placebo-controlled, multi-center Phase 3 clinical trial, TRCA-301*, in 217 chronic kidney disease (CKD) patients with metabolic acidosis. TRC101 represents a first-in-class candidate for the treatment of metabolic acidosis, a common complication of CKD that can accelerate progression of kidney disease, increase the risk of muscle wasting and cause the loss of bone density.
>
> Based on the initial topline analyses, *the TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner* ($p < 0.0001$ for all primary and secondary endpoints). TRC101 was well tolerated in the TRCA-301 trial. Both active (124 subjects) and placebo groups (93 subjects) had low discontinuation rates and low rates of treatment-related adverse events.
>
> * * *
>
> *The TRCA-301 double-blind, randomized, placebo-controlled Phase 3 trial was conducted at 47 sites in the United States and Europe* and enrolled 217

> Stage 3b or 4 CKD patients with baseline blood bicarbonate levels between 12 mEq/L and 20 mEq/L. Subjects were randomized in a 4:3 ratio to receive TRC101 or placebo. The study drug dosing (TRC101 or placebo) continued for 12 weeks once daily. The primary outcome measure was change from baseline in blood bicarbonate (Time Frame: Week 12) and included comparison of TRC101 and placebo with regard to the proportions of subjects with change from baseline in blood bicarbonate ≥ 4 mEq/L or with blood bicarbonate in the normal range (22 to 29 mEq/L). Eligible subjects that completed the TRCA-301 trial were invited to participate in a 40-week safety extension trial, TRCA-301E. *Of the 208 subjects who completed the TRCA-301 trial, 196 were enrolled in the TRCA-301E safety extension trial.*
>
> * * *
>
> Tricida, Inc., is a late-stage pharmaceutical company focused on the development and commercialization of TRC101, a non-absorbed, orally-dosed polymer drug designed to treat metabolic acidosis in patients with chronic kidney disease. The results of the pivotal Phase 3 clinical trial reported today, along with results from a successful double-blind, randomized, placebo-controlled Phase 1/2 trial and an ongoing safety extension trial, TRCA-301E, are intended to serve as the basis for the submission of a U.S. New Drug Application (NDA) for TRC101 under the Accelerated Approval Program of the U.S. Food and Drug Administration (FDA).

95. The statements identified in italics above were false and misleading. The statement that TRCA-301 was a "multi-center" trial "conducted at 47 sites in the United States and Europe" was materially false and misleading when made for two reasons, and Defendants knew or recklessly disregarded the truth in making the statement. First, most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, and second, [redacted]—both material pieces of information for an investor to be able to accurately assess the likelihood that veverimer would receive FDA approval. The omission of these facts was material and stating that the TRCA-301 trial was "multi-center" and conducted "at 47 sites in the United States and Europe" was materially misleading.

96. Demonstrating that a pivotal trial is adequate and well controlled under 21 C.F.R. § 314.126 requires showing that any foreign data are applicable to the U.S. population and U.S. medical practice. F FDA, *Guidance for Industry and FDA Staff, FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions* 9 (March 2012),

https://www.fda.gov/media/83209/download; *see also* Nancy J. Stark, *Clinical Studies: Europe or the United States?*, Medical Device & Diagnostic Industry (May 1, 2004), https://www.mddionline.com/news/clinical-studies-europe-or-united-states ("FDA's most common objection to European data is related to how representative European subjects are of the U.S. patient population."). But "geographic, socio-economic, infrastructure, cultural and educational features" of "the Eastern European nephrology community" mean that "[s]everal aspects of CKD differ significantly" compared with Western Europe, which is generally considered to be the most U.S.-like foreign region besides Canada. Mehmet Sukru Sever, et. al., *A Roadmap for Optimizing Chronic Kidney Disease Patient Care and Patient-Oriented Research in the Eastern European Nephrology Community*, Clinical Kidney J. (Dec. 22, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7857792/. Thus, the fact that a majority of trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, raised the risk that trial participants would not be sufficiently representative of the U.S. patient population and U.S. medical practice for the FDA to accept the trial results. This, in turn, was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval. Accordingly, the omission of the fact that a majority of trial sites for the Phase 3 trial were in Eastern Europe from the statement that the TRCA-301 trial was conducted "at 47 sites in the United States and Europe" rendered it false and misleading.

97. Tricida and Klaerner knew that this omission made the statement about Tricida's Phase 3 trial having been conducted "at 47 sites in the United States and Europe" false and misleading because the FDA specifically raised the issue with Tricida. [redacted]

[redacted] Tricida and Klaerner knew, or recklessly disregarded, that the FDA would carefully and critically consider *where* the patients who made up TRCA-301 were located. Despite this, [redacted]

98. Given that Tricida intended to submit an NDA predicated upon only a single pivotal Phase 3 trial, Tricida and Klaerner knew that the TRCA-301/TRCA-301E trial would receive enhanced scrutiny from the FDA. Indeed, FDA guidance makes clear that "[a] conclusion based on two persuasive studies will always be more secure than a conclusion based on a single, comparably persuasive study." FDA, *Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* 13 (May 1998), https://www.fda.gov/media/71655/download. "For this reason, reliance on only a single study will generally be limited to situations in which a trial has demonstrated a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible." *Id.* One of the characteristics the FDA looks for in a single study capable of supporting an effectiveness claim is "a large multicenter study in which (1) no single study site provided an unusually large fraction of the patients and (2) no single investigator or site was disproportionately responsible for the favorable effect seen." *Id.* Tricida and Klaerner knew the patient enrollment details for its own study, and they knew that data from one high-enrolling clinical site, [redacted], had a disproportionate impact on the trial's results. [redacted]. Tricida and Klaerner knew, or recklessly disregarded, that patients disproportionately enrolled in one trial site undermined the so-called "randomness" of the trial and undermined its credibility with the FDA. This information was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval. The omission of

this information from the statement that the Phase 3 trial was "multi-center" and "conducted at 47 sites" rendered it materially false and misleading.

99. It was also misleading to tout that TRCA-301 "met both its primary and secondary endpoints in a highly statistically significant manner" [redacted]

100. Tricida's statement that TRCA-301 had "met both its primary and secondary endpoints in a highly statistically significant manner" was further misleading [redacted]

[redacted]

Materially False and Misleading Statements and Omissions Concerning the IPO

101. On June 27, 2018, Tricida filed a Form S-1/A and related Rule 424(b)(4) Prospectus in connection with the Company's IPO ("2018 Prospectus"), both of which were signed by Defendant Klaerner. Under "Our Development Program for TRC101," the 2018 Prospectus stated,

> In May 2018, we completed our pivotal Phase 3 clinical trial, TRCA-301. The double blind, randomized, placebo-controlled trial enrolled 217 subjects with Stage 3b or 4 CKD (an estimated glomerular filtration rate, or eGFR, of 20 to 40 mL/min/1.73m2) and low blood bicarbonate levels (between 12 mEq/L and 20 mEq/L).
>
> * * *
>
> *We conducted the trial at 47 sites in the United States and Europe.*

Under "Risk Disclosures," the 2018 Prospectus stated, "*We recently completed a* randomized, double-blind, placebo-controlled, *multicenter pivotal Phase 3 clinical trial for TRC101, known as TRCA-301.*"

102. For the reasons stated in ¶¶95-98, the statements identified in italics above were materially false and misleading and omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements. [redacted] it was misleading for Defendants to omit to reveal to investors that the vast majority of the patients came from Eastern Europe and that [redacted]

103. Established knowledge about foreign patient populations and FDA guidance aside, Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 2018 Prospectus cautioned that "the FDA may determine that

clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 2018 Prospectus warned at pages 40-41,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

Not only were both statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients who are unlikely to be representative of the U.S. patient population and U.S. medical care, but they were misleading. As stated above and in ¶¶95-98, Tricida and Klaerner specifically knew the risks of using clinical data from a patient population outside the United States [redacted] Yet, Tricida and Klaerner omitted to reveal that the Phase 3 TRCA-301 trial was conducted using a patient population [redacted] from Eastern Europe—which the FDA does not consider to be applicable to a United States patient population under the circumstances—and that [redacted], making the risk disclosure not only ineffective but false and misleading.

104. The 2018 Prospectus further stated:

> Our development program for TRC101 is designed to obtain approval of TRC101 pursuant to the FDA's Accelerated Approval Program. Under the Accelerated Approval Program, we plan to pursue approval for TRC101 based upon efficacy data related to a primary endpoint measuring a change from baseline in blood bicarbonate level. We have completed a successful

> 135-subject, Phase 1/2 trial, TRCA-101, and a 217-subject, pivotal Phase 3 clinical trial, TRCA-301. Eligible subjects who completed the 12-week treatment period in our pivotal TRCA-301 trial were invited to continue in our 40-week safety extension trial, TRCA-301E, which we expect to complete in the first half of 2019. *Based on feedback from the FDA, we believe that the data from the TRCA-101, TRCA-301 and TRCA-301E trials will provide sufficient evidence of clinical safety and efficacy to support the submission and review of an NDA for TRC101 pursuant to the Accelerated Approval Program.* We plan to submit an NDA for TRC101 in the second half of 2019.

In addition to the reasons explained above in ¶¶99, 100, the statement identified in italics above was false and misleading, or omitted to disclose material facts necessary to keep it from being misleading, because [redacted]

105. Accordingly, it was materially false and misleading for Defendants to state that the FDA's "feedback" indicated that data from TRCA-301 sufficiently supported accelerated approval while failing to disclose [redacted] Defendants also had no reasonable basis to believe that the data from TRCA-301 was sufficient to support accelerated approval as [redacted]

106. The 2018 Prospectus also stated:

> *The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner* ($p < 0.0001$ for all primary and secondary endpoints). TRC101 was well tolerated in our TRCA-301 trial. Both active (124 subjects) and placebo groups (93 subjects) had low discontinuation rates and low rates of treatment-related adverse events.

* * *

Initial topline analysis of our pivotal Phase 3 clinical trial, TRCA-301, indicates that treatment with TRC101 resulted in statistically significant increases in blood bicarbonate, meeting both the primary and secondary endpoints of the trial. After 12 weeks of treatment, 59.2% of subjects in the TRC101-treated group, compared with 22.5% of subjects in the placebo group, exhibited an increase in blood bicarbonate level of at least 4 mEq/L or achieved a blood bicarbonate level in the normal range of 22 to 29 mEq/L, which was the primary endpoint of the trial. The secondary endpoint of the trial, the mean change in blood bicarbonate from baseline to week 12, was 4.49 mEq/L in the TRC101-treated group, compared with 1.66 mEq/L in the placebo group. The results of the primary and secondary endpoints were highly statistically significant ($p < 0.0001$).

107. For the reasons stated in ¶¶99, 100, the statements identified in italicsabove were materially false and misleading and omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements. [redacted]

108. Both the 2018 Prospectus and the Prospectus accompanying the April 2019 offering made the following additional statements regarding the endpoints and magnitude of the treatment effect:

> Because we are developing a product candidate for the treatment of a disease or condition ***on the basis of an unvalidated surrogate endpoint, there are increased risks that the FDA or other regulatory authorities may find that our clinical program provides insufficient evidence of clinical benefit***, may have difficulty analyzing and interpreting the results of our clinical program, and may delay or refuse to approve TRC101.
>
> In addition, we are not aware of any chronic therapeutic agent that has previously been approved by the FDA on the basis of a clinical trial that used blood bicarbonate level as the primary endpoint. We have engaged in discussions with the FDA regarding the design of our pivotal Phase 3 clinical trial, TRCA-301, and whether the use of blood bicarbonate as a surrogate endpoint is reasonably likely to predict clinical benefit. However, the FDA has discretion at any time, including during the NDA review, to determine whether there is support for the use of blood bicarbonate as a surrogate endpoint.

> ***Key issues with our endpoint include uncertainty about the degree of change from baseline blood bicarbonate that will translate into improved clinical outcomes, the population in which such change is expected to translate into improved clinical outcomes, and the need for data supporting a causal relationship between blood bicarbonate concentration and clinical outcomes. As a result, we cannot be certain that FDA will ultimately conclude that the design and results of our pivotal Phase 3 clinical trial, TRCA-301, which uses changes from baseline in blood bicarbonate level as the primary endpoint, will be sufficient for approval of TRC101.***
>
> Moreover, even if the FDA does find that changes from baseline in blood bicarbonate are sufficiently likely to predict clinical benefit for patients, ***the FDA may not agree that we have achieved the primary endpoint in our pivotal Phase 3 clinical trial, TRCA-301, to the magnitude or to the degree of statistical significance required by the FDA***. Further, even if those requirements are satisfied, the FDA also could give overriding weight to inconsistent or otherwise confounding results on other efficacy endpoints or other results of the trial, including results on secondary and exploratory endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Regulatory authorities in other countries may take similar positions.

For the reasons stated in ¶¶99, 100, the statements identified in italics above were too generalized to actually disclaim the specific issues repeatedly raised to Tricida and Klearner by the FDA. The statements were materially false and misleading and omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements. As stated in ¶¶23, 47-50, Tricida and Klaerner knew [redacted]

Materially False and Misleading Statements and Omissions Concerning the Second and Third Quarters of 2018

109. On August 9, 2018, Tricida filed its Form 10-Q for the second quarter of 2018, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 2Q18 10-Q,

pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

110. On November 8, 2018, Tricida filed its Form 10-Q for the third quarter of 2018, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 2Q18 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

111. The risk disclosures in both the 2Q18 10-Q and 3Q18 10-Q stated,

> *We recently completed a* randomized, double-blind, placebo-controlled, *multicenter pivotal Phase 3 clinical trial for TRC101, known as TRCA-301.* The TRCA-301 trial enrolled 217 CKD patients with metabolic acidosis. Eligible subjects who completed the 12-week treatment period in our pivotal Phase 3 trial were invited to continue in our 40-week safety extension trial, TRCA-301E.
>
> * * *
>
> *Our safety extension trial, TRCA-301E, is being conducted at 29 sites in the United States and Europe.*

112. For the reasons stated in ¶¶95-98, the statements identified in italics above were materially false and misleading and omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements. [redacted] it was misleading for Defendants to omit to reveal to investors that the vast majority of the patients came from Eastern Europe.

113. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 10-Qs cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and

efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Qs warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, these italicized statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients who are unlikely to be representative of the U.S. patient population and U.S. medical care, and were materially misleading. As stated above, Tricida and Klaerner knew the risks of using clinical data from a patient population outside the United States because [redacted] Additionally, the extension trial, TRCA-301E, was even less representative of the U.S. population than the 12-week TRCA-301. [redacted]

Materially False and Misleading Statements and Omissions Concerning the Full Year 2018 and the Second Public Offering

114. On March 28, 2019, Tricida held an earnings call. Klaerner reported on the call that Tricida had the results of the TRCA-301E extension trial, and that the combined results of the

TRCA-301/TRCA-301E trial "far exceeded our expectations." Not only did the extension trial "me[e]t its primary and all secondary endpoints," but "we have observed evidence of clinical benefit in TRC101-treated subjects, including reduced all-cause mortality, slowing of CKD progression and improved physical function." Klaerner stated: "we feel good about what we've learned in the 301E study regarding safety and efficacy, increasing our confidence for a successful VALOR-CKD trial."

115. The statements Klaerner made on the March 28, 2019 earnings call identified above were false and misleading, and omitted to disclose material information necessary to make them not misleading. As explained above in ¶¶99, 100, [redacted]

116. On March 29, 2019, Tricida filed its Form 10-K for the full year 2018, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 2018 10-K, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Annual Report on Form 10-K of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

117. On April 3, 2019, Tricida filed a Form S-1MEF and related Rule 424(b)(4) Prospectus in connection with the Company's secondary offering, both of which were signed by Defendant Klaerner (the "2019 Prospectus").

118. The "Business" section of the 2018 10-K and 2019 Prospectus stated, "In May 2018, we completed our pivotal Phase 3 clinical trial, TRCA-301, and in March 2019, the results of this trial were published in The Lancet.... *We conducted the trial at 47 sites in the United States and Europe*, of which 37 sites enrolled patients." The risk disclosures in the 2018 10-K and April 2019 Prospectus stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for TRC101, known as TRCA-301.... *Our extension trial, TRCA-301E, was conducted at 37 sites in the United States and Europe.*"

119. For the reasons stated in ¶¶95-98, the statements identified in italics above were materially false and misleading and omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements. [redacted], it was misleading for Defendants to omit to reveal to investors that the vast majority of the patients came from Eastern Europe.

120. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 2018 10-K and 2019 Prospectus cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-K and 2019 Prospectus warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, these italicized statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients who are unlikely to be representative of the U.S. patient population and U.S. medical care, and Defendants omitted material facts necessary to keep them from being misleading.

121. The 2018 10-K also stated:

> In May 2018, we completed our randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial, TRCA-301, in 217 CKD patients with metabolic acidosis, and in March 2019, the results of this trial were published in The Lancet. *The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner (p<0.0001 for both the primary and secondary endpoints)*. TRC101 was well tolerated in our TRCA-301 trial. One hundred ninety-six of the 208 eligible subjects who completed the 12-week treatment period in our pivotal TRCA-301 trial agreed to continue into our 40-week blinded extension trial, TRCA-301E.

122. For the reasons stated in ¶¶99, 100, the statements italicized above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading. It was misleading to characterize TRCA-301 as having "met both its primary and secondary endpoints in a highly statistically significant manner" without disclosing that [redacted]

123. The 2019 Prospectus stated:

> In May 2018, we completed our randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial, TRCA-301, in 217 CKD patients with metabolic acidosis, and in March 2019, the results of this trial were published in The Lancet. ***The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner (p<0.0001 for both the primary and secondary endpoints)***. TRC101 was well tolerated in our TRCA-301 trial. One hundred ninety-six of the 208 eligible subjects who completed the 12-week treatment period in our pivotal TRCA-301 trial agreed to continue into our 40-week blinded extension trial, TRCA-301E.
>
> ***In March 2019, we completed our TRCA-301E trial. Based on the initial topline data analyses, the TRCA-301E trial met its primary and all secondary endpoints. We believe these results provide evidence of long-term safety and tolerability of TRC101 and durability of blood bicarbonate effect.*** The placebo-adjusted improvements in favor of TRC101-treated subjects in the two measures of physical function at Week 52 approximately doubled compared to the results at Week 12 observed in the parent trial, TRCA-301. We believe the results from these two assessments provide consistent evidence of a clinically meaningful improvement in physical function and related aspects of quality of life for TRC101-treated subjects.

> The statistical analysis plan for the TRCA-301E trial also specified a comparison of the TRC101 and placebo groups for the time to the composite clinical endpoint of death (all-cause mortality), dialysis/kidney transplant (renal replacement therapy) or a ≥50% decline in estimated glomerular filtration rate (eGFR), taken together DD50. Over the combined (TRCA-301 and TRCA-301E trials) 52-week treatment period, DD50 was prolonged in the TRC101 group compared to the placebo group, with an annualized DD50 incidence rate, calculated as 100 times the number of events divided by the total person-years, of 4.2% in the TRC101 group vs 12.0% in the placebo group (p = 0.0224).

For the reasons stated in ¶¶99, 100, the statements italicized above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading. It was misleading to state that "we believe these results provide evidence of long-term safety and tolerability of TRC101 and durability of blood bicarbonate effect" without disclosing that [redacted]

Materially False and Misleading Statements and Omissions Concerning First Quarter of 2019

124. On May 10, 2019, Tricida filed its Form 10-Q for the first quarter of 2019, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 1Q19 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

125. The 1Q19 10Q stated,

> In May 2018, we completed our randomized, double-blind, placebo controlled, pivotal Phase 3 clinical trial, TRCA-301, in 217 CKD patients with metabolic acidosis. *The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner* (p < 0.0001 for both the primary and secondary endpoints). *One hundred ninety-six of the 208 subjects who completed the 12-week treatment period in our pivotal Phase 3 trial, TRCA-301, agreed and were eligible to continue in our extension trial,* TRCA-301E, which we completed in March 2019.

126. For the reasons stated in ¶¶99, 100, the statements identified in italics above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading. As stated above, it was misleading to characterize TRCA-301 as having "met both its primary and secondary endpoints in a highly statistically significant manner" without disclosing that [redacted]

127. It was also misleading to tout that 196 out of 208 subjects who completed the 12-week TRCA-301 trial continued on to the 40-week TRCA-301E extension when [redacted]

128. The risk disclosures in the 1Q19 10-Q stated,

> In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301.
>
> * * *
>
> Our 40-week extension trial, TRCA-301E, *was conducted at 37 sites in the United States and Europe.*

129. For the reasons stated in ¶¶95-98, the statements identified in italics above were false and misleading, omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements.

130. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 1Q19 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials

> should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, these italicized statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients [redacted], and Defendants omitted material facts necessary to keep them from being misleading.

Materially False and Misleading Statements and Omissions at the Goldman Sachs Global Healthcare Conference

131. On June 12, 2019, Defendant Klaerner spoke at the Goldman Sachs Global Healthcare Conference:

> Graig Suvannavejh Goldman Sachs Group Inc., Research Division – Executive Director & Senior Equity Research Analyst:
>
> I think it's fascinating. So veverimer is your lead program. And it's -- how would you describe what's unique about that? And maybe that transition to kind of the clinical data that you've generated for that program?
>
> Gerrit Klaerner Tricida, Inc. – Founder, President, CEO & Executive Director:
>
> Yes. Let's start with the most recent news, which, in my career, I've never experienced. We set out to do a 1-year extension study, where we hope to see good safety, which we did. We hoped to see continued durable effect of our surrogate marker, which is basically the increase of serum bicarbonate. And on top of it, in this blinded placebo-controlled study, we actually saw a reduced all-cause mortality, reduced number of patients requiring dialysis and fewer patients having -- losing 50% of the kidney function.

> And when you fast-forward in all the work that we've done, from a discovery to an early development, to a late stage development, ***agreeing with FDA, an accelerated approval path, you*** -- *all you expect to do is to show a surrogate effect, and then you have a post-marketing commitment that ultimately then, you confirm that, that surrogate is going to translate.*
>
> Now we found ourselves with 1-year safety extension data that showed clinical benefit. And I think that excitement, you can feel now, I think, in the company, both from interacting with payers, interacting with physicians, interacting with regulators, I think that is a good thing to have.

132. For the reasons stated in ¶¶99, 100, the statements identified in italics above were false and misleading, or omitted to disclose material information necessary to prevent them from being misleading. Klaerner knew these statements to be false and misleading or was reckless is his disregard for the truth when he made them.

133. Additionally, Klaerner materially misrepresented that Tricida had reached agreement with the FDA regarding TRCA-301's and TRCA-301E's endpoints. [redacted]

Materially False and Misleading Statements and Omissions Concerning the Second Quarter of 2019

134. On August 9, 2019, Tricida filed its Form 10-Q for the second quarter of 2019, which was signed by Defendant Klaerner.

135. Klaerner certified in Exhibit 31.1 to the 2Q19 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the

circumstances under which such statements were made, not misleading with respect to the period covered by this report."

136. The August 9, 2019 10-Q stated:

> In May 2018, we completed our randomized, double-blind, placebo controlled, pivotal Phase 3 clinical trial, TRCA-301, in 217 CKD patients with metabolic acidosis. *The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner* ($p < 0.0001$ for both the primary and secondary endpoints). *One hundred ninety-six of the 208 subjects who completed the 12-week treatment period in our TRCA-301 trial* agreed *and were eligible to continue in our 40-week extension trial, TRCA-301E, which we completed in March 2019*. The TRCA-301E trial met its primary and all secondary endpoints.

137. For the reasons stated in ¶¶99, 100, the statements identified in italics above were false and misleading and omitted to disclose material facts necessary to keep them from being misleading. It was misleading to characterize TRCA-301 as having "met both its primary and secondary endpoints in a highly statistically significant manner" without disclosing that [redacted]

138. As stated above in ¶¶127, it was also misleading to tout that 196 out of 208 subjects who completed the 12-week TRCA-301 trial continued on to the 40-week TRCA-301E extension, [redacted]

139. The risk disclosures in the 2Q19 10-Q stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301.... Our 40-week extension trial, TRCA-301E, *was conducted at 37 sites in the United States and Europe*."

140. The statements identified in italics above were false and misleading, and omitted material information. In addition to the reasons explained above in ¶¶95-98, [redacted]

[redacted]

141. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 2Q19 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, 140, these italicized statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients [redacted], and Defendants omitted material facts necessary to keep them from being misleading.

Materially False and Misleading Statements and Omissions Concerning the Third Quarter of 2019

142. On November 14, 2019, Tricida filed its Form 10-Q for the third quarter of 2019, which was signed by Defendant Klaerner.

143. Klaerner certified in Exhibit 31.1 to the 3Q19 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

144. The November 14, 2019 10-Q stated:

> In May 2018, we completed our randomized, double-blind, placebo controlled, pivotal Phase 3 clinical trial, TRCA-301, in 217 CKD patients with metabolic acidosis. *The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner* ($p < 0.0001$ for both the primary and secondary endpoints). *One hundred ninety-six of the 208 subjects who completed the 12-week treatment period in our TRCA-301 trial agreed and were eligible to continue in our 40-week extension trial,* TRCA-301E, which we completed in March 2019. The TRCA-301E trial met its primary and all secondary endpoints.

145. For the reasons stated in ¶¶99, 100, 127, the statements identified in italics above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading.

146. The risk disclosures in the 3Q19 10-Q stated,

> In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301.
>
> * * *
>
> *Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe.*

147. For the reasons stated in ¶¶95-98, 140, the statements identified in italics above were false and misleading, or omitted to disclose material facts necessary to keep them from being

misleading. As stated above, Tricida and Klaerner knew, or recklessly disregarded, that characterizing the trials as being conducted in "the United States and Europe" was false and misleading because [redacted].

148. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 3Q19 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, 140, these italicized statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients [redacted], and Defendants omitted material facts necessary to keep them from being misleading.

Materially False and Misleading Statements and Omissions Concerning the Fourth Quarter and Year 2019

149. On March 2, 2020, Tricida filed its Form 10-K for the year 2019, which was signed by Defendant Klaerner.

150. Klaerner certified in Exhibit 31.1 to the 2019 10-K, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Annual Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

151. The "Business" section of the 10-K stated,

> *We conducted the [TRCA-301] trial at 47 sites in the United States and Europe*, of which 37 sites enrolled patients.
>
> * * *
>
> *Based on the magnitude of the increase in serum bicarbonate observed in our pivotal Phase 3 trial, TRCA-301, and the inverse relationship between serum bicarbonate and risk of renal events described by the Predictive MA Model, we have determined that randomizing 1,600 subjects* to veverimer or placebo in a 1:1 ratio will result in 90% power to show a 30% to 35% reduction in renal events in the VALOR-CKD trial.

152. The risk disclosures stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301.... *Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe*."

153. In addition to the reasons stated in ¶¶95-98, 140, the statements identified in italics above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading. [redacted]

[redacted]

154. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 2019 10-K cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-K warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, 140, 153, these italicized statements were too generalized to disclaim the specific risk at issue but demonstrate Defendants' knowledge of the specific risk and were actually false and misleading. [redacted]

[redacted]

155. The 2019 10-K also contained false and misleading statements about the Phase 3 trial's results, specifically about the trial having met its primary and secondary endpoints:

> The TRCA-301 trial was a double-blind, placebo-controlled trial that randomized 217 patients with non-dialysis dependent CKD and metabolic acidosis. ***The trial met both its primary and secondary endpoints in a highly statistically significant manner (p<0.0001 for both the primary and secondary endpoints).*** Veverimer was well tolerated in our TRCA-301 trial. The primary endpoint of the trial measured improvements in serum bicarbonate levels in veverimer-treated patients versus placebo. Serum bicarbonate is a surrogate measure of metabolic acidosis and a persistent serum bicarbonate level below 22 mEq/L indicates metabolic acidosis. ***After 12 weeks of treatment, 59.2% of subjects in the veverimer-treated group, compared with 22.5% of subjects in the placebo group, had an increase in serum bicarbonate level of at least 4 mEq/L or achieved a serum bicarbonate level in the normal range of 22 to 29 mEq/L, which was the primary endpoint of the trial. The secondary endpoint of the trial, the least squares, or LS, mean change from baseline to week 12 in serum bicarbonate, was 4.42 mEq/L in the veverimer-treated group, compared with 1.78 mEq/L in the placebo group. The mean change in serum bicarbonate from baseline to week 12 was 4.5 mEq/L in the veverimer-treated group, compared with 1.7 mEq/L in the placebo group.***

156. The statements identified above in italics were false and misleading because they misrepresented veverimer's true chances of approval based on the results of the Phase 3 trial and omitted core issues with the trial's efficacy endpoints, as described above in ¶¶99, 100, 127, [redacted]

[redacted]

[redacted]

157. The 2019 10-K also stated that "We believe that the data from the TRCA-101, TRCA-301 and TRCA-301E clinical trials will provide sufficient clinical evidence of safety and efficacy to support the approval of our NDA for veverimer pursuant to the Accelerated Approval Program." In addition to the reasons stated in ¶¶99, 100, 127, this statement was false and misleading, and omitted material information, for failing to disclose the "Significant Issue" of the magnitude of the treatment effect on blood bicarbonate and the ability of TRCA-303 to confirm a treatment benefit, as stated by the FDA to Tricida on January 27, 2020. Neither Tricida nor Klaerner could reasonably have believed that the data from the clinical trials would provide sufficient clinical evidence of safety and efficacy to support an NDA after the specific negative feedback they received from the FDA at the January 27, 2020 mid-cycle meeting.

Materially False and Misleading Statements and Omissions Concerning the First Quarter of 2020

158. On May 7, 2020, Tricida held its 1Q20 earnings call with analysts. During the call, Klaerner stated,

> In our Day 74 letter, *the FDA indicated that they plan to hold an advisory committee meeting or AdCom to discuss the application. In our late-cycle meeting with the FDA held in May 2020, the FDA indicated it currently does not plan to hold an AdCom to discuss veverimer due in part to the logistical challenges posed by COVID-19. In our late-cycle meeting with FDA, we took the opportunity to address outstanding review issues.* We presented our data and rationale as to *why we think we very much satisfied the requirements for initial approval under the Accelerated Approval Program including the magnitude and durability of the treatment effect on the surrogate markup serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials.*
>
> Under the initial approval, *we have to ensure that US patients who would be prescribed veverimer get clinically significant benefit that outweighs the risk of treatment. Overall, while the FDA continues its review, we remain*

confident that our submission meets the standard for approval through the Accelerated Approval Program.

159. The statements identified in italics above were false and misleading. Klaerner made multiple false and misleading statements on the May 7, 2020 conference call by failing to disclose material information necessary to render the statements true in the context in which they were made. First, the reason why the FDA "indicated it currently does not plan to hold an AdCom to discuss veverimer" was not due to the "logistical challenges posed by COVID-19," [redacted] Klaerner therefore knew, or recklessly disregarded, that there would be no AdCom meeting because of the significant issues with Tricida's application of Accelerated Approval.

160. It was also misleading for Klaerner to state that he was "confident" that Tricida's "submission me[t] the standard for approval through the Accelerated Approval Program" [redacted]

161. It was further misleading for Klaerner to state that Tricida had satisfied the requirements for Accelerated Approval by demonstrating a treatment effect on SBC of sufficient "magnitude and durability" [redacted]

[redacted]

162. Plus, by discussing the data underling the clinical trial and the "outstanding clinical review issues" Klaener misled investors by omitting to reveal [redacted], as stated in ¶¶95-98, 140, 153. Tricida confirmed as much in its 2Q20 10-Q, filed August 6, 2020, in which the Company disclosed,

> In our late cycle meeting with the FDA, held in May 2020, we addressed two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population.

[redacted]. Given the magnitude of these issues, the Company said in the 2Q20 10-Q that it was likely to receive a CRL. These review issues proved to be the main reasons for the FDA's rejection of veverimer, as the Company finally spelled out in a February 25, 2021, press release titled "Tricida Has Received an Appeal Denied Letter from the Office of New Drugs of the FDA in Response to its Formal Dispute Resolution Request":

> In the ADL, the OND acknowledged that the TRCA-301/TRCA-301E trial met its serum bicarbonate endpoints with statistical significance but concluded that the extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression. The OND also concluded that the confirmatory trial, VALOR-CKD, is underpowered to detect the effect size (13%) predicted by the original Tangri model (also known as the Predictive MA Model) based upon the placebo-subtracted mean treatment effect observed in the TRCA-301/TRCA-301E trial.
>
> The OND also provided feedback on other concerns that are particularly relevant in an NDA supported by a single registrational trial. The OND noted concerns around the trial results being strongly influenced by a single

site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population.

163. Klaerner either knew, or recklessly disregarded, that these issues presented a significant obstacle to the approval of veverimer [redacted]

166. Klaerner's false statements were material because they concealed the true risk that the FDA would reject the veverimer NDA.

167. On May 8, 2020, Tricida filed its Form 10-Q for the first quarter of 2020, which was signed by Defendant Klaerner.

168. Klaerner certified in Exhibit 31.1 to the 1Q20 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

169. The risk disclosures section stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301…. *Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe.*"

170. For the reasons stated in ¶¶95-98, 140, 153, 165, the statements identified in italics above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading. As stated above, Tricida and Klaerner knew, or recklessly disregarded, that characterizing the trials as being conducted in "the United States and Europe" was misleading [redacted]

171. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 1Q20 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include*

> *differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, 140, 153, 165 these italicized statements were too generalized to disclaim the specific risk at issue but demonstrate Defendants' knowledge of the specific risk and were actually false and misleading. While the risk factors above characterized the risk of the FDA not accepting foreign data as a hypothetical (*e.g.*, "the FDA *may* not accept such foreign clinical data"), [redacted]. Stating that differences in clinical conditions and study populations "may" affect the acceptance of the foreign data was likewise misleading [redacted]

Materially False and Misleading Statements and Omissions Concerning Second Quarter 2020

172. On Augnst 5, 2020, after Tricida first disclosed limited information that the FDA had identified deficiencies with its NDA, Tricida held an earnings call earnings call to discuss its second quarter 2020 financial results. On the earnings call, an analyst asked Klaerner to "remind us of the process that you went through to get the FDA to sign off on the design of the pivotal study and in particular, the serum bicarbonate primary endpoint. Was there any disagreement between you and the FDA in the design? Or are you both on the same page?" Klaerner offered a carefully worded response, stating the Company had reached agreement with the FDA (1) "that we are treating a serious disease, that there is an unmet medical need and that we have a

surrogate that's likely going to translate to clinical benefit," and (2) on "a quantitative understanding … of how the surrogate really impacts … the progression of kidney disease." Based on those agreements, said Klaerner, Tricida designed the TRCA-301/TRCA-301E and VALOR-CKD trials.

173. Klaerner's response to the analyst's question was materially false and misleading for the reasons stated in ¶¶ 99, 100,127 157. [redacted] "quantitative understanding … of how the surrogate really impacts the progression of kidney disease."

THE TRUTH BEGINS TO EMERGE

174. On July 15, 2020, after the close of trading, Tricida issued a press release revealing that the FDA notified Tricida on July 14, 2020 that the Agency had "identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." Tricida said the notification did not "specify the deficiencies identified by the FDA," but "[t]he Company plans to work with the FDA to identify and seek to resolve the deficiencies." Klaerner was quoted in the press release, stating "We are surprised and disappointed by this news …. We continue to believe in the potential of veverimer to be disease modifying and our goal is to work with FDA to identify and resolve the issues in order to bring veverimer to patients."

175. In response to this news, the price of Tricida common stock fell $10.56 per share to close at $15.64 per share on July 16, 2020.

176. The July 15, 2020, press release publicly revealed for the first time that there were issues with the veverimer NDA, but Defendants still withheld material information from the investing public. Tricida and Klaerner were well aware of the deficiencies referenced by the FDA, i.e., that the majority of trial sites were in Eastern Europe and one site in particular was disproportionately responsible for the trial's enrollment, [redacted] Defendants had just met with the FDA in May 2020 for a late-cycle review, during which the FDA specifically raised concerns about the ability of the surrogate endpoint for the TRCA-301/TRCA-301E trial to demonstrate likely clinical

effect as well as the comparability of the trial subjects to the U.S. patient population and U.S. medical practice. Moreover, these had been long-standing points of discussion with the FDA throughout the clinical trials. And Defendants also knew that an NDA supported by a phase 3 program consisting of only a single pivotal trial, such as the veverimer NDA, would receive heightened scrutiny from the FDA. The press release indicated that the NDA would not be approved by the PDUFA date, but the details would have made clear that the NDA was nowhere near approval—i.e., it could not be salvaged by a short-term fix. The failure to mention these facts withheld key pieces of the whole truth.

177. On August 24, 2020, at 8:30 am, prior to the opening of trading, Tricida issued a press release announcing that it [had] received a Complete Response Letter ("CRL") from the FDA for its veverimer NDA on August 21, 2020:

> According to the CRL, the FDA is seeking additional data beyond the TRCA-301 and TRCA-301E trials regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and the applicability of the treatment effect to the U.S. population. FDA also expressed concern as to whether the demonstrated effect size would be reasonably likely to predict clinical benefit. There were no safety, clinical pharmacology/biopharmaceutics, CMC or non-clinical issues identified in the CRL.
>
> The CRL provided multiple options for resolving the identified deficiencies. In order to obtain approval for veverimer the company may or may not have to conduct an additional clinical trial. The FDA indicated it is willing to meet with Tricida to discuss options for obtaining approval, including under the Accelerated Approval Program.
>
> "We have collaborated with the FDA on the Accelerated Approval Program for veverimer and while we are disappointed to receive this CRL, we are pleased that the FDA has provided helpful, specific comments and indicated their willingness to continue to work with us to pursue approval of veverimer," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We remain confident in the fundamentals of, and unmet medical need for, veverimer and we continue to conduct our confirmatory trial, VALOR-CKD." Tricida plans to request a Type A meeting with the FDA in the coming weeks. A Type A meeting is usually scheduled within 30 days of the meeting request. Following the Type A meeting, anticipated early in the fourth quarter, Tricida plans to provide an update on next steps and estimated timing of a potential resubmission of the NDA.

178. Tricida's stock price fell by $3.13 per share, or 24% on this news, falling from its prior closing price of $13.24 per share to close at $10.11 per share on August 24, 2020.

179. The August 24, 2020, press release revealed for the first time the FDA's position that the Phase 3 TRCA-301/TRCA-301E trial was inadequate on its own to demonstrate the efficacy of veverimer. It also revealed that the FDA required additional data regarding the applicability of the observed treatment effect to the U.S. population. However, the press release went to great lengths to temper the true nature of these issues by suggesting that there were no severe obstacles to near-term approval and emphasizing (1) the "multiple options for resolving the identified deficiencies," (2) Klaerner's pleasure about the FDA's feedback, and (3) the Company's confidence in the "fundamentals" of veverimer, such that the VALOR-CKD trial was continuing unchanged. The press release failed to mention the numerous issues specific to having relied upon a single pivotal Phase 3 trial and otherwise hid the severity of the issues that it did share.

180. On October 29, 2020, Tricida announced that during an End-of-Review Type A conference held October 20, 2020, with the FDA's Division of Cardiology and Nephrology—which had issued the CRL on August 21, 2020, denying Tricida's veverimer NDA—the FDA told Tricida that it was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would therefore "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program." But because Tricida could not provide this interim information from the VALOR-CKD trial "without compromising the integrity of the ongoing trial," additional trials would be required to gather this information. In other words, the FDA rejected the veverimer NDA because Tricida had failed to demonstrate that the single phase 3 trial's surrogate endpoint could reasonably predict clinical efficacy. Tricida suggested that this was the first time the FDA had called into question Tricida's use of serum bicarbonate to measure efficacy, noting that the Company's discussions with the FDA over nearly four years "focused on development of veverimer based solely on the use of serum bicarbonate as the surrogate endpoint to enable accelerated approval, with CKD progression data to be provided only at the completion of the VALOR-CKD trial." [redacted]

[redacted]

[redacted] The same press release disclosed that Tricida was "significantly reducing its headcount from 152 to 59 people and will discuss its commitments with vendors and contract service providers to potentially provide additional financial flexibility."

181. In response to this news, Tricida's stock price fell $3.90 per share, to close at $4.37 per share on October 29, 2020.

182. The October 29, 2020, press release revealed for the first time that Tricida would have to provide clinical evidence of CKD progression (instead of just chemical evidence of serum bicarbonate levels), and that that evidence would have to come from the VALOR-CKD trial or some other yet-to-be designed trial. However, acquiring that evidence from the VALOR-CKD trial would eliminate its ability to function as a confirmatory postmarketing trial for purposes of the accelerated approval process. The press release still said nothing about either the numerous issues specific to having relied upon a single pivotal Phase 3 trial [redacted] Although the announced reduction in headcount suggested that near-term commercialization of veverimer was not likely, the press release emphasized that there was still a path forward because the company "plans to wait for formal meeting minutes from the FDA related to the End-of-Review Type A meeting prior to determining how to proceed with obtaining regulatory approval for veverimer."

183. On December 8, 2020, sixteen minutes before trading closed for the day, Tricida announced that it had revised the protocol for the VALOR-CKD trial to replace an "adaptive design" and "interim analysis for sample size adjustment" with "a group sequential design" and "an unblinded interim analysis for early stopping for efficacy." Tricida had scrapped plans providing any semblance of near-term approval prospects for veverimer. The press release also provided an update on the regulatory status of the veverimer NDA:

> A Formal Dispute Resolution Request (FDRR) has been submitted to the FDA to seek clarity on the path forward for resubmitting our New Drug Application (NDA) through the Accelerated Approval Program. The FDRR requests that the Office of New Drugs (OND) find that the magnitude of serum bicarbonate change seen in the TRCA-301 and TRCA-301E trials is reasonably likely to predict clinical benefit in the treatment of metabolic acidosis associated with CKD and that it can therefore serve as the basis for accelerated approval. If accepted for consideration, a decision on the FDRR

> is expected in the first quarter of 2021. The timing and next steps for a resubmission of the NDA for veverimer will be dependent upon the OND's decision.
>
> "We believe that we are studying the right patient population and the right CKD progression endpoint in VALOR-CKD. Hence, we believe that an adaptive design is no longer necessary and have locked in the sample size at 1,600 subjects and built in two opportunities for stopping early for efficacy over the next 18 to 24 months, in the event that the effect of veverimer on slowing CKD progression is greater than currently modeled," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "And while we are disappointed that we could not come to a resolution with the Division of Cardiology and Nephrology on the resubmission of our NDA during our Type A meeting, we believe that the focused, single issue FDRR currently represents the best approach to bring veverimer to patients through accelerated approval."

184. The press release, like earlier press releases, focused on one issue with the NDA: the surrogate endpoint's ability to predict clinical benefit. This time, the press release presented a new way—the FDRR—for the FDA to approve the NDA. Importantly, the press release still said nothing about either the numerous issues specific to having relied upon a single pivotal Phase 3 trial. Tricida's stock price fell from its closing price of $8.12 per share on December 8, 2020, to close at $6.68 per share on December 9, 2020, an almost 18% decline.

185. Twenty-five minutes before markets closed on February 25, 2021, Tricida announced in a press release that the Company had "received an Appeal Denied Letter (ADL), from the Office of New Drugs (OND) of the FDA in response to its Formal Dispute Resolution Request (FDRR) submitted in December 2020." According to Tricida, the FDA's ADL said the "extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression," and "the confirmatory trial, VALOR-CKD, is underpowered …." The press release also publicly revealed for the first time the FDA's "concerns that are particularly relevant in an NDA supported by a single registration trial": the trial results were "strongly influenced by a single site," and "the majority of sites for the TRCA-301/TRCA-301E trial" were in Eastern Europe, "where differences in patient management … might affect the treatment response to veverimer," rendering questionable "the applicability to a U.S. patient population." This press release finally revealed the numerous

deficiencies plaguing the veverimer NDA, all of which the Company had known about long before it even submitted the NDA.

186. On this news, Tricida's stock price fell from $7.36 per share at close on February 25, 2021 to $5.11 per share at close on February 26, 2021.

ADDITIONAL ALLEGATIONS OF SCIENTER

187. Throughout the class period, Defendant Klaerner sold nearly $10 million in shares of Tricida stock. When he made these sales of Tricida stock, he was privy to the complete—and nonpublic—collection of risks related to the veverimer NDA's likelihood for FDA approval. He knew that his and Tricida's failure to disclose the full risk profile for veverimer's FDA review had inflated the value of Tricida stock. He has only made a single purchase of Tricida stock (ever), which occurred on July 2, 2018. He purchased 15,790 shares at a price of $19.00 apiece. He made 34 sales of Tricida stock between December 26, 2018 and February 8, 2021, totaling $9,758,875. His sales were particularly aggressive from March 28, 2019—days before the secondary public offering—and December 18, 2019—while the hype of the recently-filed veverimer NDA remained fresh—during which period Tricida's stock consistently traded at prices between $30 and $43.50 per share. His trades during the class period were as follows:

Date	Transaction	Share Price	Shares Traded	Sum
02/08/21	Sell	$7.26	8,000	$58,080
01/13/21	Sell	$7.39	16,690	$123,292
01/12/21	Sell	$7.65	9,821	$75,131
01/11/21	Sell	$7.49	21,489	$160,953
07/15/20	Sell	$26.33	4,000	$105,320
07/01/20	Sell	$27.15	4,000	$108,600
06/15/20	Sell	$25.97	4,000	$103,869
06/01/20	Sell	$26.23	4,000	$104,920
05/15/20	Sell	$31.55	4,000	$126,220
05/01/20	Sell	$27.98	4,000	$111,906
04/15/20	Sell	$27.47	4,000	$109,891
04/06/20	Sell	$24.22	4,000	$96,880
03/16/20	Sell	$23.91	4,000	$95,640
03/02/20	Sell	$31.53	4,000	$126,120
02/18/20	Sell	$36.10	4,000	$144,400
02/03/20	Sell	$36.33	4,000	$145,330

01/15/20	Sell	$35.26	4,000	$141,040
01/02/20	Sell	$37.15	4,000	$148,607
12/18/19	Sell	$38.91	31,750	$1,235,457
12/11/19	Sell	$43.50	7,572	$329,346
12/10/19	Sell	$43.28	3,948	$170,869
12/01/19	Sell	$39.65	8,000	$317,160
11/01/19	Sell	$38.54	49,000	$1,888,556
10/28/19	Sell	$37.26	4,000	$149,035
10/01/19	Sell	$31.07	11,223	$348,663
09/30/19	Sell	$30.69	10,255	$314,734
08/28/19	Sell	$33.71	4,000	$134,840
07/29/19	Sell	$31.17	4,000	$124,680
07/06/19	Sell	$35.55	5,826	$207,097
07/03/19	Sell	$37.08	6,874	$254,854
03/28/19	Sell	$32.96	57,822	$1,905,974
03/04/19	Sell	$23.76	853	$20,267
03/01/19	Sell	$23.94	7,147	$171,064
12/26/18	Sell	$25.02	4,000	$100,080
07/02/18	Buy	$19.00	15,790	$300,010

Most of these trades occurred as part of a 10b5-1 plan, but this 10b5-1 plan was itself first implemented amidst Klaerner and Tricida's ongoing securities fraud (which began as of the IPO). Indeed, Tricida made materially false statements about the TRCA-301 trial before shares of the Company were even available to the investing public. Klaerner traded on the nonpublic knowledge of the inflated value of Tricida's stock throughout the class period.

188. Tricida itself engaged in insider trades through the initial public offering on June 28, 2018, and again in the secondary offering on April 3-8, 2019. Tricida needed funds to operate and continue its postmarketing trials of veverimer so it sold common stock to the investing public in its IPO. Thereafter, it was in need of additional monies to fund its operations past early 2021, when the Company would be in the initial stages of commercializing veverimer if the NDA were approved by the PDUFA date in August 2020. Tricida had $243.4 million in cash, cash equivalents, and investments at the end of 2018. At the time of the secondary offering, however, Tricida already knew of the significant risks in obtaining FDA approval for veverimer and failed to reveal these material facts to investors. Indeed, Tricida knew that most of the TRCA-301/301E trials had been conducted in Eastern Europe and that one trial site in particular had a disproportionate effect on

the results, both of which severely undercut the credibility of the study results [redacted] Tricida sold 6.44 million shares of common stock, at $36 per share, for over $231 million by the time the secondary stock offering completed on April 8, 2019.

189. Tricida had only one drug candidate: veverimer. Accordingly, the day-to-day operations at the Company leading up and throughout the Class Period focused solely on shepherding veverimer through clinical trials and FDA approval to commercialization; the Company's entire future hung on the success of bringing veverimer to market. And Tricida was Klaerner's project through and through. He "started it in 2013 in his living room" shortly after "finishing up the Relypsa experience" and he "was looking for an opportunity to create something that is truly disease-modifying." Klaerner, who has a Ph.D. in polymer and organic chemistry and was an in-house scientist before founding several companies, is "very passionate about polymer chemistry," and demonstrates himself to be intimately familiar with the design and functionality of veverimer. Thus, Klaerner, as CEO was involved in and aware of even more than just the core operations at Tricida.

190. He was focused on the details and, given the small size and narrow focus of the Company, participated in meetings with lower-level employees working toward accomplishing a single component of the data needed to support an NDA. Klaerner attended meetings with and inspections by the FDA, including the May 6. 2015 meeting, the November 30, 2016 meeting, the February 9, 2017 meeting, the July 26, 2017 meeting, the March 6, 2018 meeting, the June 3, 2019 meeting, the January 27, 2020 meeting, and the May 1, 2020 meeting. Additionally, the Establishment Inspection Report for the inspection of Tricida's South San Francisco facility from December 9-17, 2019, reports that the FDA inspector met with Klaerner before the facility inspection and afterwards to debrief the results. Additionally, Confidential Witness 2 ("CW2")—who served in the role of Executive Director of Operations from September 2019 through October 2020 and was responsible for overseeing the commercialization of veverimer after (hopeful) FDA approval—stated that at numerous meetings, Klaerner told the assembled company executives that he was waiting to hear from the FDA about setting up a meeting with the Agency.

LOSS CAUSATION / ECONOMIC LOSS

191. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially inflated the price of Tricida stock and operated as a fraud or deceit on Class Period purchasers of Tricida stock by misrepresenting and omitting material information about the design and execution of the TRCA-301/TRCA-301E trials. When Defendants' prior misrepresentations and omissions were disclosed to the market, beginning on July 15, 2020, Tricida's stock price fell as the prior artificial inflation came out of the price. The full inflation did not come out of the stock price until February 25, 2021. As a result of their purchases of Tricida stock during the Class Period, Lead Plaintiff and other members of the Class suffered economic loss, i.e., damages, under the federal securities laws.

192. Defendants' misleading statements and omissions of material facts, identified herein at ¶¶94-173, had the intended effect and caused Tricida stock to trade at artificially inflated prices during the Class Period.

193. As a direct result of the disclosures that began after the markets closed on July 15, 2020, as detailed in ¶¶174-76, Tricida's stock price suffered a significant decline. On July 16, 2020, the price of Tricida stock, which traded on NASDAQ, fell from the prior days close of $26.20 to a low of $15.64, a drop of 40.31% after the market learned that Tricida's veverimer NDA suffered from review issues that were significant enough to preclude discussions of labeling and postmarketing requirements/commitments.

194. In addition, the disclosure made before the markets opened on August 24, 2020, as detailed in ¶¶177-79, directly caused Tricida's stock price to fall. On August 24, 2020, Tricida's stock price fell from a close of $13.24 per share on August 21, 2020, to close at $10.11 per share—a drop of 23.64%—after learning that Tricida had received a CRL from the FDA in response to the veverimer NDA.

195. The disclosure before the markets opened on October 29, 2020, as detailed in ¶¶180-82, also had a direct impact on Tricida's stock price. The price of Tricida's stock plummeted from $8.27 at close on October 28, 2020, to $4.37 at close on October 29, 2020—a drop of 47.16%—in direct response to additional disclosures regarding review issues with the veverimer

NDA and its likelihood for near-term approval. Specifically, Tricida revealed that the FDA told Tricida that it was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would therefore "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program."

196. Tricida's stock price again suffered as a direct result of the disclosures made sixteen minutes before the markets closed on December 8, 2020, as detailed in ¶¶183-84, which revealed (1) that Tricida had failed to come to an agreement with the FDA on the resubmission of the veverimer NDA during the Type A meeting, (2) that the Company had filed a FDRR in an attempt to convince the FDA that the TRCA-301 trial results are reasonably likely to predict clinical benefit, and (3) that the Company had scrapped the protocol for the VALOR-CKD trial. In direct response, Tricida's stock price fell 17.73% from $8.12 per share at close on December 8, 2020 to close at $6.68 per share on December 9, 2020.

197. The final disclosures on February 25, 2021, as detailed in ¶¶185-86, directly caused Tricida's stock price to fall from $7.36 per share at close on February 25, 2021 to close at $5.11 on February 26, 2021—a drop of 30.57%. Twenty-five minutes before the markets closed on February 25, 2021, Tricida disclosed that it had received an ADL from the FDA, which determined (1) the "extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression," (2) "the confirmatory trial, VALOR-CKD, is underpowered," (3) the trial results were "strongly influenced by a single site," and (4) "the majority of sites for the TRCA-301/TRCA-301E trial" were in Eastern Europe, "where differences in patient management … might affect the treatment response to veverimer," rendering questionable "the applicability to a U.S. patient population."

198. The declines in Tricida's stock price on July 16, 2020, August 24, 2020, October 29, 2020, December 8, 2020, and February 25, 2021, were a direct result of the nature and extent of Defendants' prior misstatements and omissions being revealed to investors and the market.

199. The timing and magnitude of Tricida's stock price decline negates any inference that the losses suffered by Lead Plaintiffs and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific factors unrelated to

Defendants' fraudulent conduct. On July 16, 2020, the Nasdaq was down only -0.7%, with the Nasdaq U.S. Smart Pharmaceuticals Index down even less, at -0.4%. On August 24, 2020, the Nasdaq increased 0.01%, and the Nasdaq Smart Pharma was down only -0.3%. On October 29, 2020, the Nasdaq increased 1.6% and the Nasdaq Smart Pharma increased 0.4%. On December 8, 2020, the Nasdaq decreased 0.02% and the Nasdaq Smart Pharma increased 1.46%. On February 25, 2021, the Nasdaq decreased 0.04%, while the Nasdaq Smart Pharma decreased -1.5%.

200. The losses suffered by Lead Plaintiff and other members of the Class were a direct result of Defendants' fraudulent scheme to inflate Tricida's stock price and the subsequent, significant declines in the value of that stock when Defendants' prior misrepresentations and omissions were revealed.

CLASS ACTION ALLEGATIONS

201. Lead Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), on behalf of a class consisting of all purchasers of the common stock of Tricida during the Class Period (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

202. The members of the Class are so numerous that joinder of them is impracticable. Throughout the Class Period, Tricida traded on the NASDAQ exchange. While the exact number of class members is not presently known to Lead Plaintiff, and can only be ascertained through discovery, Lead Plaintiff believes there are thousands of members in the proposed Class. Record owners and other members of the Class can be ascertained through records maintained by Tricida and/or its transfer agent. Those record holders could be notified of the pendency of this action by mail.

203. Lead Plaintiff's claims are typical of the claims of the members of the Class, as all are similarly affected by Defendants' wrongful conduct in violation of federal law.

204. Lead Plaintiff will fairly and adequately protect the interests of the members of the class and has retained competent and experienced securities litigation counsel.

205. Common questions of law and fact exist as to all members of the Class and will predominate over any questions solely affecting individual members of the Class. Among the common questions of law and fact common to the Class:

a. Whether the Exchange Act was violated by Defendants as alleged herein;

b. Whether statements made by Defendants misrepresented and omitted material facts about Tricida's business, operations, and management; and

c. To what extent the members of the Class have suffered damages, and the proper measure of those damages.

206. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, given that joinder of all members is impracticable. As the damages suffered by each individual Class member may be relatively small, the burden and expense of litigating individual cases would make it all but impossible for many members of the Class to redress wrongs done to them. There will not be any difficulty in managing this action as a class action.

FRAUD ON THE MARKET

207. Lead Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine. Among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. These omissions and material misrepresentations were material;

c. Tricida common stock traded in an efficient market throughout the Class Period;

d. The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Tricida common stock; and

e. Lead Plaintiff and other members of the Class purchased Tricida common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

208. At all relevant times, the market for Tricida common stock was efficient, as:

a. Tricida filed periodic public reports with the SEC as a regulated issuer; and

b. Tricida regularly communicated with public investors via established communications mechanisms, including through the regular dissemination of press releases on major news wire services, communications through the financial press, securities analysts, the internet, and other similar reporting services.

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

209. Lead Plaintiff incorporates ¶¶1-208 by reference.

210. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and concealed material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

211. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

212. Employed devices, schemes, and artifices to defraud;

213. Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

214. Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Tricida securities during the Class Period.

215. In addition to the duties of full disclosure imposed on Defendants as a result of their affirmative false and misleading statements to the public, the Exchange Act Defendants had a duty to promptly disseminate truthful information with respect to Tricida's operations and performance that would be material to investors in compliance with the integrated disclosure provisions of the SEC, including with respect to the Company's revenue and earnings trends, so that the market prices of the Company's securities would be based on truthful, complete, and accurate information. SEC Regulations S-X (17 C.F.R. §210.01, et seq.) and S-K (17 C.F.R. §229.10, et seq.).

216. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the Class have suffered damages in connection with their respective purchases of Tricida common stock during the Class Period, because, in reliance on the integrity of the market, they paid artificially inflated prices for Tricida securities and experienced losses when the artificial inflation was released from Tricida securities as a result of the revelations and prices decline detailed herein. Plaintiffs and the Class would not have purchased Tricida securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

217. By virtue of the foregoing, Tricida and Klaerner have each violated §10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

COUNT II

For Violations of Section 20(a) of the Exchange Act Against Defendant Klaerner

218. Lead Plaintiff incorporates ¶¶1-208 by reference.

219. During his tenure as officer and director of Tricida, Klaerner and Tricida were controlling persons of the Company within the meaning of §20(a) of the Exchange Act. By reason of their positions of control and authority as officer and director of Tricida, Klaerner and Tricida had the power and authority to cause Tricida to engage in the conduct complained of herein. These defendants were able to, and did, control, directly and indirectly, the decision-making of Tricida, including the content and dissemination of Tricida's public statements and filings described herein, thereby causing the dissemination of the materially false and misleading statements and omissions as alleged herein. Tricida exercised control over and directed the actions of its senior managers, directors and agents, including Defendant Klaerner. Tricida controlled Defendant Klaerner and all of its employees and subsidiaries.

220. In his capacity as chief executive officer and director of Tricida, and as more fully described herein, Defendant Klaerner participated in the misstatements and omissions set forth above. Indeed, Klaerner had direct and supervisory involvement in the day-to-day operations of the Company and had access to non-public information regarding Tricida's deceptive and risky business practices. Defendants had the ability to influence and direct and did so influence and

direct the activities of Defendants in their violations of §10(b) of the Exchange Act and Rule 10b-5 as detailed in ¶¶211-19.

221. As a result, Defendants were control persons within the meaning of §20(a) of the Exchange Act.

222. As set forth above, Tricida violated §10(b) of the Exchange Act. By virtue of its position, and as a result of its aforementioned conduct and culpable participation, Tricida is liable pursuant to §20(a) of the Exchange Act, jointly and severally with, and to the same extent as Defendant Klaerner is liable to Plaintiffs and the other members of the Class. Tricida exercised control over Klaerner and all of its employees and subsidiaries and, as a result of its aforementioned conduct and culpable participation, is liable pursuant to §20(a) of the Exchange Act, jointly and severally with, and to the same extent as the Klaerner is liable to Plaintiffs and the other members of the Class.

223. This claim is brought within the applicable statute of limitations.

224. By reason of the foregoing, Defendants violated §20(a) of the Exchange Act, 15 U.S.C. §78(a).

PRAYER FOR RELIEF

225. WHEREFORE, Lead Plaintiff prays for relief and judgment as follows:

a. Declaring the action to be a proper class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein;

b. Awarding all damages and other remedies available under the Securities Exchange Act in favor of Lead Plaintiff and all members of the Class against Defendants in an amount to be proven at trial, including interest thereon;

c. Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

d. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

226. Lead Plaintiff demands a trial by jury.

December 15, 2022

Respectfully submitted,

/s/ Jacob A. Walker

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EXHIBIT B

Fill in this information to identify the case:

Debtor Tricida, Inc.

United States Bankruptcy Court for the: _____ District of Delaware (State)

Case number 23-10024

Official Form 410
Proof of Claim

04/22

Read the instructions before filling out this form. This form is for making a claim for payment in a bankruptcy case. Do not use this form to make a request for payment of an administrative expense. Make such a request according to 11 U.S.C. § 503.

Filers must leave out or redact information that is entitled to privacy on this form or on any attached documents. Attach redacted copies or any documents that support the claim, such as promissory notes, purchase orders, invoices, itemized statements of running accounts, contracts, judgments, mortgages, and security agreements. **Do not send original documents;** they may be destroyed after scanning. If the documents are not available, explain in an attachment.

A person who files a fraudulent claim could be fined up to $500,000, imprisoned for up to 5 years, or both. 18 U.S.C. §§ 152, 157, and 3571.

Fill in all the information about the claim as of the date the case was filed. That date is on the notice of bankruptcy (Form 309) **that you received.**

Part 1: Identify the Claim

1. **Who is the current creditor?**
   Jeffrey Fiore
   Name of the current creditor (the person or entity to be paid for this claim)
   Other names the creditor used with the debtor _____

2. **Has this claim been acquired from someone else?**
   ☑ No
   ☐ Yes. From whom? _____

3. **Where should notices and payments to the creditor be sent?**
   Federal Rule of Bankruptcy Procedure (FRBP) 2002(g)

Where should notices to the creditor be sent?	**Where should payments to the creditor be sent?** (if different)
See summary page	
Contact phone 973-597-2500	Contact phone _____
Contact email lsklar@lowenstein.com	Contact email _____

   Uniform claim identifier for electronic payments in chapter 13 (if you use one):
   _

4. **Does this claim amend one already filed?**
   ☑ No
   ☐ Yes. Claim number on court claims registry (if known) _____ Filed on _____ MM / DD / YYYY

5. **Do you know if anyone else has filed a proof of claim for this claim?**
   ☑ No
   ☐ Yes. Who made the earlier filing? _____

2310024230308000000000006

Part 2: Give Information About the Claim as of the Date the Case Was Filed

6. **Do you have any number you use to identify the debtor?**

☑ No

☐ Yes. Last 4 digits of the debtor's account or any number you use to identify the debtor: ___ ___ ___ ___

7. **How much is the claim?** $ unliquidated. **Does this amount include interest or other charges?**

☐ No

☐ Yes. Attach statement itemizing interest, fees, expenses, or other charges required by Bankruptcy Rule 3001(c)(2)(A).

8. **What is the basis of the claim?**

Examples: Goods sold, money loaned, lease, services performed, personal injury or wrongful death, or credit card.

Attach redacted copies of any documents supporting the claim required by Bankruptcy Rule 3001(c).

Limit disclosing information that is entitled to privacy, such as health care information.

Violations of Federal Securities Laws - see addendum

9. **Is all or part of the claim secured?**

☑ No

☐ Yes. The claim is secured by a lien on property.

Nature or property:

☐ Real estate: If the claim is secured by the debtor's principle residence, file a *Mortgage Proof of Claim Attachment* (Official Form 410-A) with this *Proof of Claim*.

☐ Motor vehicle

☐ Other. Describe: _____

Basis for perfection: _____

Attach redacted copies of documents, if any, that show evidence of perfection of a security interest (for example, a mortgage, lien, certificate of title, financing statement, or other document that shows the lien has been filed or recorded.)

Value of property: $_____

Amount of the claim that is secured: $_____

Amount of the claim that is unsecured: $_____ (The sum of the secured and unsecured amount should match the amount in line 7.)

Amount necessary to cure any default as of the date of the petition: $_____

Annual Interest Rate (when case was filed)_____%

☐ Fixed

☐ Variable

10. **Is this claim based on a lease?**

☑ No

☐ Yes. **Amount necessary to cure any default as of the date of the petition.** $_____

11. **Is this claim subject to a right of setoff?**

☑ No

☐ Yes. Identify the property: _____

23100242303080000000000006

12. **Is all or part of the claim entitled to priority under 11 U.S.C. § 507(a)?**

A claim may be partly priority and partly nonpriority. For example, in some categories, the law limits the amount entitled to priority.

		Amount entitled to priority
☑	No	
☐	Yes. *Check all that apply:*	
☐	Domestic support obligations (including alimony and child support) under 11 U.S.C. § 507(a)(1)(A) or (a)(1)(B).	$
☐	Up to $3,350* of deposits toward purchase, lease, or rental of property or services for personal, family, or household use. 11 U.S.C. § 507(a)(7).	$
☐	Wages, salaries, or commissions (up to $15,150*) earned within 180 days before the bankruptcy petition is filed or the debtor's business ends, whichever is earlier. 11 U.S.C. § 507(a)(4).	$
☐	Taxes or penalties owed to governmental units. 11 U.S.C. § 507(a)(8).	$
☐	Contributions to an employee benefit plan. 11 U.S.C. § 507(a)(5).	$
☐	Other. Specify subsection of 11 U.S.C. § 507(a)(__) that applies.	$

* Amounts are subject to adjustment on 4/01/25 and every 3 years after that for cases begun on or after the date of adjustment.

13. **Is all or part of the claim pursuant to 11 U.S.C. § 503(b)(9)?**

☑ No

☐ Yes. Indicate the amount of your claim arising from the value of any goods received by the debtor within 20 days before the date of commencement of the above case, in which the goods have been sold to the Debtor in the ordinary course of such Debtor's business. Attach documentation supporting such claim.

$_____

Part 3: Sign Below

The person completing this proof of claim must sign and date it. FRBP 9011(b).

If you file this claim electronically, FRBP 5005(a)(2) authorizes courts to establish local rules specifying what a signature is.

A person who files a fraudulent claim could be fined up to $500,000, imprisoned for up to 5 years, or both. 18 U.S.C. §§ 152, 157, and 3571.

Check the appropriate box:

☐ I am the creditor.

☑ I am the creditor's attorney or authorized agent.

☐ I am the trustee, or the debtor, or their authorized agent. Bankruptcy Rule 3004.

☐ I am a guarantor, surety, endorser, or other codebtor. Bankruptcy Rule 3005.

I understand that an authorized signature on this *Proof of Claim* serves as an acknowledgement that when calculating the amount of the claim, the creditor gave the debtor credit for any payments received toward the debt.

I have examined the information in this *Proof of Claim* and have reasonable belief that the information is true and correct.

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

Executed on date 03/08/2023
MM / DD / YYYY

/s/Lindsay Sklar
Signature

Print the name of the person who is completing and signing this claim:

Name: Lindsay Sklar
First name Middle name Last name

Title: Counsel

Company: Lowenstein Sandler LLP
Identify the corporate servicer as the company if the authorized agent is a servicer.

Address

Contact phone _____ Email _____

23100242303080000000000006

KCC ePOC Electronic Claim Filing Summary

For phone assistance: Domestic 866-476-0898 | International 001-310-823-9000

Debtor:
23-10024 - Tricida, Inc.
District:
District of Delaware

Creditor:
Jeffrey Fiore
Lowenstein Sandler LLP
Attn: Michael Etkin, Andrew Behlmann, Lindsay Skla
One Lowenstein Drive
Roseland, New Jersey, 07068
USA
Phone:
973-597-2500
Phone 2:
Fax:
973-597-2400
Email:
lsklar@lowenstein.com

Has Supporting Documentation:
Yes, supporting documentation successfully uploaded
Related Document Statement:

Has Related Claim:
No
Related Claim Filed By:

Filing Party:
Authorized agent

Other Names Used with Debtor:

Amends Claim:
No
Acquired Claim:
No

Basis of Claim:
Violations of Federal Securities Laws - see addendum

Last 4 Digits:
No

Uniform Claim Identifier:

Total Amount of Claim:
unliquidated

Includes Interest or Charges:
None

Has Priority Claim:
No

Priority Under:

Has Secured Claim:
No
Amount of 503(b)(9):
No
Based on Lease:
No
Subject to Right of Setoff:
No

Nature of Secured Amount:
Value of Property:
Annual Interest Rate:
Arrearage Amount:
Basis for Perfection:
Amount Unsecured:

Submitted By:
Lindsay Sklar on 08-Mar-2023 3:14:36 p.m. Eastern Time
Title:
Counsel
Company:
Lowenstein Sandler LLP

VN: E2C03C5750C22684CA0DC0F3B4997CDD

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	Chapter 11
TRICIDA, INC.,[1]	Case No. 23-10024 (JTD)
Debtor.	(Jointly Administered)

ADDENDUM TO PROOF OF CLAIM

1. This Proof of Claim is submitted by the claimant identified in the attached proof of claim ("Claimant"). Claimant is the court-appointed lead plaintiff in the securities class action styled as *Michael Pardi v. Tricida, Inc. and Gerrit Klaerner, Case No. 4:21-cv-00076-HSG* (the "Securities Litigation"), pending in the United States District Court for the Northern District of California, Oakland Division (the "District Court").

2. On July 29, 2022, the District Court upheld in part a complaint against the Debtor and its CEO, Gerrit Klaerner (collectively, "Defendants"), for violations of Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §78(a); and United States Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder. Following this ruling, and after discovery commenced, Claimant obtained documents from the United States Food and Drug Administration and used that evidence to file the *Second Amended Complaint for Violations of the Federal Securities Laws* on December 15, 2022 (the "Amended Complaint") [Securities Litigation Docket No. 115] against Defendants. A copy of the Amended Complaint is attached hereto as Exhibit A and incorporated herein by reference. All references herein to the Amended Complaint are qualified in their entirety by the Amended Complaint

[1] The Debtor in this chapter 11 case, together with the last four digits of the Debtor's federal tax identification number, is Tricida, Inc. (2526). The Debtor's service address is 7000 Shoreline Court, Suite 201, South San Francisco, CA 94080.

itself. The Amended Complaint re-asserts the theory already upheld and adds additional evidence of wrongdoing by Defendants. For the avoidance of doubt, this Proof of Claim is submitted in Claimant's individual capacity.

3. By operation of the automatic stay pursuant to 11 U.S.C. § 362, the Securities Litigation is stayed solely with respect to the Debtor. Accordingly, on January 24, 2023, Claimant filed a motion to voluntarily dismiss the Debtor as a defendant without prejudice.

4. As of January 11, 2023 (the "Petition Date"), and continuing up to and including the present, the Debtor was and remains liable to Claimant for damages in an amount not yet determined, plus interest, costs, and attorneys' fees as allowed (the "Claim"). The allegations in the Amended Complaint, as may be further amended from time to time, form the basis of the Claim. The basis of the Claim against the Debtor (as well as of Claimant's claims against Mr. Klaerner and any other defendants to be named in the Securities Litigation) is damages resulting from violations of the federal securities laws by Defendants in connection with the purchase or other acquisition by Claimant of securities issued by or on behalf of the Debtor.[2]

5. The Claim is not founded upon a specific writing, although certain documents, too voluminous and burdensome to annex hereto, which upon information and belief, relate to the Debtor's violations of the federal securities laws from which the Claim arises, and which include, but are not limited to, documents filed with the United States Securities and Exchange Commission, are available. In addition, certain of these documents, as well as other documents, may become available through discovery with respect to the Claim.

6. No payments have been made on account of the Claim.

7. The Claim is not subject to any setoff or counterclaim.

[2] Claimant reserves the right to amend the description of the Claim from time to time, including but not limited to asserting additional bases for the Claim, in connection with any amendment of the Complaint and/or the discovery of additional information relevant to the Claim.

8. No security interest is held for the Claim.

9. The Claim is asserted in addition to, and not in lieu of, all other claims that Claimant may have against the Debtor, its affiliates, Mr. Klaerner, and any other defendants to be named in the Securities Litigation.

10. Claimant reserves all rights (including but not limited to arguments, counterarguments, and defenses) in connection with the Securities Litigation. Claimant further reserves all rights with respect to the Claim and this proof of claim, including but not limited to the right to amend and/or supplement this proof of claim from time to time and/or move to withdraw the bankruptcy reference.

11. This proof of claim and any subsequent appearance, pleading, claim, or suit made by Claimant shall not be deemed to:

- constitute a submission by Claimant to the jurisdiction of the Bankruptcy Court;
- constitute consent by Claimant to entry by the Bankruptcy Court of any final order in any non-core proceeding, **which consent is hereby withheld unless expressly granted in the future with respect to a specific issue, matter, or proceeding**;
- waive any substantive or procedural rights of Claimant, including but not limited to (a) the right to challenge the constitutional authority of the Bankruptcy Court to enter a final order or judgment, or any order having the effect of a final order or judgment, on any matter; (b) the right to have final orders in non-core matters entered only after *de novo* review by a United States District Court; (c) the right to trial by jury in any proceedings so triable herein, in the Securities Litigation, or in any other case, controversy, or proceeding related to or arising from the

Debtors, this chapter 11 case, any related proceedings, or the Securities Litigation; (d) the right to have the applicable United States District Court withdraw the reference in any matter subject to mandatory or discretionary withdrawal; (e) the right to request that the Bankruptcy Court abstain from hearing the merits of the Claim pursuant to 28 U.S.C. § 1334(c); (f) the right to assert any and all claims or rights against others jointly or severally liable for the sums claimed herein; or (g) all other rights, claims, actions, arguments, counterarguments, defenses, setoffs, or recoupments to which Claimant is or may be entitled under agreements, at law, in equity, or otherwise, all of which rights, claims, actions, arguments, counterarguments, defenses, setoffs, and recoupments are expressly reserved, nor shall this proof of claim be deemed to constitute consent to electronic service of any pleading or papers for which mailed or personal service is required under any applicable law, rule, regulation, or order.

EXHIBIT A
Amended Complaint

Jeffrey C. Block, *pro hac vice*
Jacob A. Walker (SBN 271217)
Michael D. Gaines, *pro hac vice*
BLOCK & LEVITON LLP
260 Franklin Street, Suite 1860
Boston, MA 02110
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jeff@blockleviton.com
michael@blockleviton.com

Attorneys for Lead Plaintiff Jeffrey M. Fiore and the Class

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

MICHAEL PARDI, *Individually and on Behalf of All Others Similarly Situated,* Plaintiff, v. TRICIDA, INC. and GERRITT KLAERNER, Defendants.	Case No. 4:21-cv-00076-HSG **SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **[REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED]** **Class Action** ***Demand for Jury Trial***

1. Lead Plaintiff alleges the following based upon the investigation conducted by and through his attorneys, Block & Leviton LLP. This investigation included, but was not limited to review and analysis of (i) Tricida's public filings with the U.S. Securities and Exchange Commission ("SEC"), (ii) transcripts of Tricida's public conference calls, (iii) Tricida's press releases, (iv) independent media reports regarding Tricida, (v) securities analysts' reports and advisories about the Company, (vi) other public statements issued by the Company, (vii) media reports about the Company, and (viii) documents produced during pre-trial discovery by the United States Food and Drug Administration ("FDA"). Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION

2. This is a securities class action alleging violations of §§10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5, 17 C.F.R. § 240.10b-5, as promulgated thereunder, against Defendants Tricida, Inc. ("Tricida" or the "Company") and Gerrit Klaerner, Ph.D. who founded Tricida and has served as Tricida's Chief Executive Officer and President since August 2013 and is a member of its Board of Directors.

3. This action is brought on behalf of all investors who purchased Tricida common stock during the period June 28, 2018 through February 25, 2021 (the "Class Period").

4. The case concerns materially false and misleading statements and omissions of material facts about Tricida's attempts to gain approval from the FDA for its lead investigational drug candidate, veverimer (TRC101), "a non-absorbed, orally administered polymer designed to treat metabolic acidosis by binding and removing acid from the gastrointestinal tract." Veverimer is intended to slow the progression of chronic kidney disease ("CKD") through the treatment of metabolic acidosis.

5. Tricida conducted a single Phase 3 study for veverimer and sought approval under the FDA's Accelerated Drug Application ("ADA") program. To obtain approval under the ADA, a pharmaceutical company also must conduct a valid post-marketing trial.

6. In May 2018, before the Class Period begins, Tricida completed its phase 3 study for veverimer ("TRCA-301"). In a press release dated June 5, 2018, Tricida announced that TRCA-301, "was conducted at 47 sites in the United States and Europe," and "met both its primary and secondary endpoints in a statistically significant manner."

7. Based on the purported strength of these trial results, Tricida went public on June 28, 2018, selling 13,455,000 million shares of its common stock to the class at $19 per share (including the exercise of options by the underwriters of the offering) and raising $255.6 million. Shares began to trade on Nasdaq on June 28, 2018. The offering registration statement, and its accompanying prospectus (the "2018 Prospectus"), misrepresented material facts and omitted to reveal material facts necessary to make the statements that were made therein, not materially misleading.

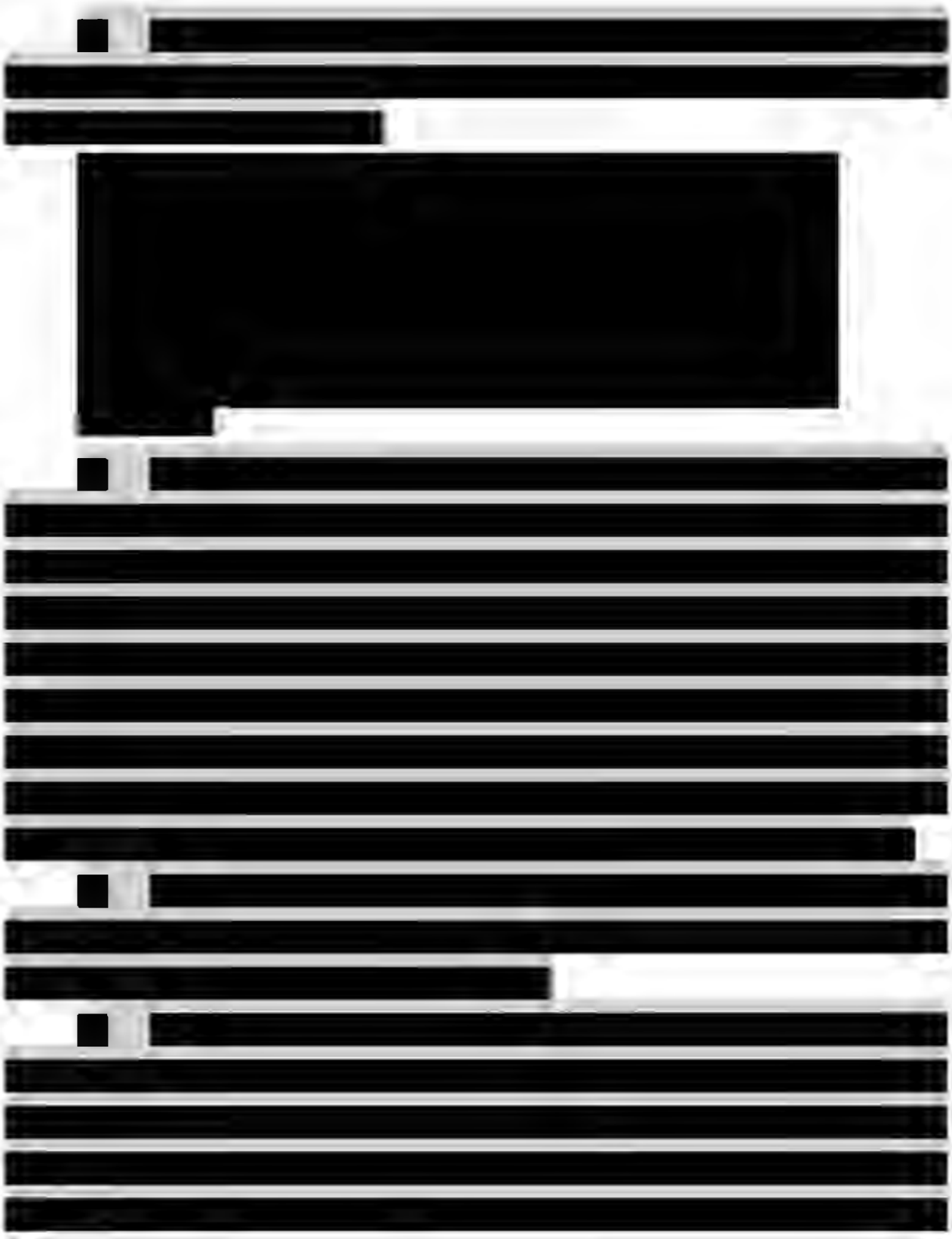
8. In the 2018 Prospectus, Defendants misrepresented that *"[b]ased on feedback from the FDA*, we believe that the data from the TRCA-101, TRCA 301 and TRCA 301E trials will provide sufficient evidence of clinical safety and efficacy to support the submission and review of an NDA for TRC101 pursuant to the Accelerated Approval Program." 2018 Prospectus at 4. (Emphasis added.)

9. The FDA, however, provided Defendants with specific feedback making the claim that the trials would "provide sufficient evidence of clinical safety and efficacy" materially false and misleading.

[redacted]

[redacted]

[redacted]



21. [redacted] Tricida informed its investors in its 2019 Form 10-K, filed with the SEC on March 2, 2020, that "[w]e believe that the

data from the TRCA-101, TRCA-301 and TRCA 301E clinical trials *will provide sufficient clinical evidence of safety and efficacy to support the approval of our NDA* for veverimer pursuant to the Accelerated Approval Program." (Emphasis added).

22. This statement was materially false and misleading when made. [redacted] Defendants had no basis to claim a belief that the clinical trials provided "sufficient clinical evidence of safety and efficacy to support the approval of our NDA."

[redacted]

[redacted]

26. But on May 7, 2020, during Tricida's 1Q20 earnings call with analysts, Klaerner misrepresented [redacted]:

> In our Day 74 letter, the FDA indicated that they plan to hold an advisory committee meeting or AdCom to discuss the application. *In our late-cycle*

> *meeting with the FDA held in May 2020, the FDA indicated it currently* does *not plan to hold an AdCom to discuss veverimer due in part to the logistical challenges posed by COVID-19. In our late-cycle meeting with FDA, we took the opportunity to address outstanding review issues.* We presented our data and rationale as to why *we think we very much satisfied the requirements for initial approval under the Accelerated Approval Program including the magnitude and durability of the treatment effect on the surrogate markup serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials.*
>
> Under the initial approval, we have to ensure that US patients who would be prescribed veverimer get clinically significant benefit that outweighs the risk of treatment. *Overall, while the FDA continues its review, we remain confident that our submission meets the standard for approval through the Accelerated Approval Program.*

(emphasis added). [redacted] Klaerner blamed the cancellation of the AdCom meeting on COVID-19. This was false. Plus, by purporting to reveal discussions with the FDA from the May 2020 late-cycle meeting, [redacted] Klaerner misleadingly inflated veverimer's likelihood of FDA approval to investors.

27. Tricida would later have more to say about the late cycle meeting (in its Second Quarter 10-Q filed with the Securities and Exchange Commission ("SEC") on August 6, 2020):

> In our late cycle meeting with the FDA, held in May 2020, we addressed two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population.[1]

But Tricida did not reveal the entire truth as to the reasons underlying why the FDA found the data supporting TRCA-301 to be insufficient until it revealed its receipt of the ADL on February 25, 2021.

28. On July 15, 2020, at 5 pm. after the close of trading, Tricida issued a press release revealing that it had received a notification from the FDA "stating that, as part of its ongoing review of the Company's [NDA], the FDA has identified deficiencies that preclude discussion of

[1] Tricida also stated for the first time that it anticipated receiving a Complete Response Letter ("CRL") for its veverimer NDA, but misleadingly feigned ignorance as to the reasons why.

labeling and postmarketing requirements/commitments at this time…. The notification does not specify the deficiencies identified by the FDA." While the notification itself may not have specified the "deficiencies identified by the FDA," Tricida already knew of those deficiencies from its May 2020 meeting and continued to conceal them from investors. Tricida's stock price plunged on July 16, 2020, on this news, falling 40% from its closing price of $26.20 per share on July 15, 2020, to close at $15.64 on July 16, 2020, wiping out over $530 million in market capitalization.

29. Tricida issued a press release on August 24, 2020, at 8:30 am, prior to the opening of trading, that it received a Complete Response Letter ("CRL") from the FDA for its NDA for veverimer. Tricida disclosed, among other things, that "According to the CRL, the FDA is seeking additional data beyond the TRCA-301 and TRCA-301E trials regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and the applicability of the treatment effect to the U.S. population. FDA also expressed concern as to whether the demonstrated effect size would be reasonably likely to predict clinical benefit." Tricida's stock price fell by $3.13 per share, or 24% on this news, wiping out approximately $157 million in market capitalization.

30. On October 29, 2020, before markets opened, Tricida announced that during an End-of-Review Type A conference held October 20, 2020, with the FDA's Division of Cardiology and Nephrology—which had issued the CRL on August 21, 2020, denying Tricida's veverimer NDA—the FDA told Tricida that it was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would therefore "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program." But because Tricida could not provide this interim information from the VALOR-CKD trial "without compromising the integrity of the ongoing trial," additional trials would be required to gather this information. In other words, the FDA rejected the veverimer NDA because the single phase 3 trial's surrogate endpoint was not an adequate stand-in for clinical efficacy. The same press release disclosed that Tricida was "significantly reducing its headcount from 152 to 59 people and will discuss its commitments with vendors and contract service providers to potentially provide additional financial flexibility."

31. In response to this news, Tricida's stock price fell 47% from its closing price of $8.27 per share on October 28, 2020, to close at $4.37 per share on October 29, 2020, wiping out nearly another $200 million in market capitalization.

32. Tricida issued a press release on December 8, 2020, sixteen minutes before markets closed for the day, announcing that the Company had failed to "come to a resolution with the Division of Cardiology and Nephrology on the resubmission of our NDA during our Type A meeting," submitted a Formal Dispute Resolution Request arguing that the TRCA-301 trial results are reasonably likely to predict clinical benefit, and revised the protocol for the VALOR-CKD trial. On this news, Tricida's stock price fell 17.73%, from a close of $8.12 per share on December 8, 2020, to close at $6.68 per share on December 9, 2020, wiping out yet another $72 million in market capitalization

33. Twenty-five minutes before markets closed on February 25, 2021, Tricida announced that it had received an ADL from the FDA. The ADL concluded (1) the "extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression," (2) "the confirmatory trial, VALOR-CKD, is underpowered," (3) the trial results were "strongly influenced by a single site," and (4) "the majority of sites for the TRCA-301/TRCA-301E trial" were in Eastern Europe, "where differences in patient management … might affect the treatment response to veverimer," rendering questionable "the applicability to a U.S. patient population." This was the first time Tricida revealed to investors that the trial results were "strongly influenced by a single site" and that the "majority of sites" for the trials were in Eastern Europe. Tricida's stock price fell 30.57% in response to these revelations, from a closing price of $7.36 per share on February 25, 2021, to $5.11 per share a close on February 26, 2021, wiping out $93 million more in market capitalization.

34. Lead Plaintiff, Jeffrey M. Fiore, and all other investors purchased Tricida common stock at artificially inflated prices and were damaged as the truth was revealed and the artificial inflation was eliminated.

JURISDICTION AND VENUE

35. This Complaint asserts claims under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b-5").

36. This Court has jurisdiction over the subject matter of this action under Section 27 of the Exchange act, 15 U.S.C. § 78aa and 28 U.S.C. §§ 1331 and 1337.

37. Venue is proper in this District under Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b), (c), and (d). Many of the acts and omissions that constitute the alleged violations of law, including the dissemination to the public of untrue statements of material facts, occurred in this District.

38. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of national securities exchanges.

PARTIES

39. Lead Plaintiff Jeffrey M. Fiore, a resident of Texas, purchased Tricida common stock during the Class Period on the Nasdaq Global Select Market and was damaged thereby. *See* ECF No. 12-2, Ex. B.

40. Defendant Tricida is a Delaware corporation with principal executive offices located at 7000 Shoreline Court, Suite 201, South San Francisco, California 94080. Tricida common stock trades in an efficient market on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "TCDA." Since its founding in 2013, the Company has incurred significant operation losses and had yet to develop any drug that the FDA approved for marketing and sales in the United States. Tricida is a control person of Gerrit Klaerner within the meaning of § 20(a) of the Exchange Act.

41. Defendant Gerrit Klaerner, Ph.D. founded Tricida and has served as Tricida's Chief Executive Officer and President since August 2013. He has also held a seat on Tricida's board of directors since July 2013. Previously, Klaerner founded Relypsa, Inc., serving as President and

Director from October 2007 until June 2013. Before that, Klaener co-founded Ilypsa, Inc., serving as its Director of Technology Assessment and Business Development from January 2003 until December 2006, and as its Chief Business Officer and Senior Vice President from December 2006 until July 2007. Before Ilypsa, Klaerner was employed at Symyx Technologies, Inc. as a Staff Scientist, Senior Staff Scientist, and Director Business Development. Klaerner attended meetings with and inspections by the FDA, including the May 6. 2015 meeting, the November 30, 2016 meeting, the February 9, 2017 meeting, the July 26, 2017 meeting, the March 6, 2018 meeting, the June 3, 2019 meeting, the January 27, 2020 meeting, and the May 1, 2020 meeting. Additionally, the Establishment Inspection Report for the inspection of Tricida's South San Francisco facility from December 9-17, 2019, reports that the FDA inspector met with Klaerner before the facility inspection and afterwards to debrief the results.

42. Prior to and during the Class Period, Klaerner was responsible for complying with the Company's Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics deemed Klaerner, as Chief Executive Officer, one of the three "sole authorized spokepersons for the Company." Klaerner made or had authority over the content and dissemination of the false and misleading statements and omissions set forth herein and is liable for those false statements and omissions. Klaerner is also a control person of Tricida within the meaning of § 20(a) of the Exchange Act.

BACKGROUND

43. A healthy kidney filters toxins and other harmful substances, including acid, from the blood. Patients suffering from chronic kidney disease ("CKD"), however, have a compromised ability to excrete acid via their kidneys. Consequently, CKD patients can develop metabolic acidosis – an excessive buildup of acid in body fluids. If not treated, Metabolic acidosis can result in progression of CKD, muscle breakdown, the development or exacerbation of bone disease, and death.

44. Metabolic acidosis in patients with CKD is often treated in the U.S. with oral alkali supplements, such as oral antacids. However, alkali supplements reduce acid levels at the cost of raising sodium levels in the body, which can in turn worsen conditions that commonly accompany

CKD, such as hypertension and heart failure. Consequently, alkali supplements typically cannot be used in patients with anything more than mild cases of metabolic acidosis, and there exists an unmet need for safe and effective treatments for metabolic acidosis in patients with CKD.

45. Tricida, founded in 2013, is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of non-absorbed therapies. Its lead investigational drug candidate is veverimer (TRC101), "a non-absorbed, orally administered polymer designed to treat metabolic acidosis by binding and removing acid from the gastrointestinal tract." Veverimer is intended to bind with hydrochloric acid in the gastrointestinal tract, thereby purporting to slow the progression of CKD through the treatment of metabolic acidosis.

46. Tricida planned to submit its NDA for veverimer to the FDA for review through the Agency's ADA. Under the ADA, if the Phase 3 program demonstrates clinical efficacy by achieving a predetermined surrogate endpoint, actual clinical efficacy (*e.g.* reduced progression of CKD) must thereafter be demonstrated through a confirmatory postmarketing trial. Tricida sought to use blood serum bicarbonate ("SBC") levels as a surrogate endpoint.

TRICIDA'S INTERACTIONS WITH THE FDA

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

62. In May 2018, Tricida completed the single veverimer Phase 3 trial, TRCA-301. In announcing the trial's results, Tricida described TRCA-301 as a "multicenter, randomized, double-blind, placebo controlled" clinical trial. The Company announced on June 5, 2018, that TRCA-301, which "was conducted at 47 sites in the United States and Europe," "met both its primary and secondary endpoints in a statistically significant manner" and that 196 of the 217 CKD patients from the Phase 3 TRCA-301 trial agreed to continue their participation in a 40-week blinded extension trial (TRCA-301E).

63. Tricida knew that the majority of trial sites were in Eastern Europe and that a single site was almost entirely responsible for the trial's favorable results. [redacted]

[redacted]

65. Nonetheless, capitalizing on what it presented as positive Phase 3 trial results, Tricida made an initial public offering ("IPO") of stock on June 28, 2018 and sold approximately $255 million in common stock to the class. The 2018 Prospectus touted the success of the TRCA-301 trial and represented that "[b]ased on feedback from the FDA, we believe that the data from the TRCA-101, TRCA-301, and TRCA-301E trials will provide sufficient evidence of clinical safety and efficacy to support the submission and review of an NDA for TRC101 pursuant to the [ADA]."

66. During an earnings call on March 28, 2019, Klaerner reported that Tricida had the results of TRCA-301's extension trial, TRCA-301E, which continued on with willing participants for 40 additional weeks after TRCA-301's 12-week run. Klaerner reported that the combined results of the TRCA-301/TRCA-301E trial "far exceeded our expectations": Not only did the extension trial "me[e]t its primary and all secondary endpoints," but "we have observed evidence of clinical benefit in TRC101-treated subjects, including reduced all-cause mortality, slowing of CKD progression and improved physical function." Klaerner shared that "we feel good about what we've learned in the 301E study regarding safety and efficacy, increasing our confidence for a successful VALOR-CKD trial."

67. Tricida and Klaerner repeated the same statements about the success of the Phase 3 pivotal trial, its extension, and the design of the confirmatory postmarketing trial (without mentioning any of their known critical shortcomings) in each and every Tricida SEC filing and quarterly earnings call through May 2020.

68. During the Q4 2018 earnings call on March 28, 2019, Chief Financial Officer Geoffrey M. Parker reported that Tricida's cash, cash equivalents, and investments totaled $243.4 at the end of 2018, which, in conjunction with a recently amended debt facility, would only allow the Company to fund its "anticipated operating expenses and capital expenditure requirements into 2021," i.e. "the initial commercial launch period for TRC101." The Company had raised

approximately $255 million in its initial public offering in June 2018, so without the funds raised in the offering, at that point in time, Tricida, would have been out of cash. Tricida needed additional money to fund anything other than a flawless accelerated approval of veverimer, and even then, there was not enough cash to fully commercialize the drug. Based on the publicly-presented prospects for FDA approval for veverimer, Tricida sold 6.44 million shares of common stock, at $36 per share, for over $231 million in a secondary stock offering completed on April 8, 2019.

[redacted]

71. On September 4, 2019, Tricida announced that it had submitted the veverimer NDA through the ADA in late August 2019. And on November 14, 2019, Tricida announced that the FDA had accepted its NDA for review under the ADA and assigned a Prescription Drug User Fee Act ("PDUFA") date of August 22, 2020. Tricida also mentioned that enrollment in the VALOR-CKD trial was estimated to be completed in mid-2020.

72. [redacted]

[redacted]

[redacted]

[redacted]

77. The late-cycle meeting itself took place on May 1, 2020. [redacted]

78. On July 14, 2020, Tricida received a letter [redacted]

TRICIDA AND KLAERNER REVEAL THE FDA'S CONCERNS PIECEMEAL

79. Tricida announced in a press release on, July 15, 2020, that it had received a notification from the FDA "stating that, as part of its ogoing review of the Company's [NDA], the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time…. The notification does not specify the deficiencies identified by the FDA." In response to this news, on unusually heavy trading activity, Tricida's stock price dropped sharply in one day, falling $10.56 per share in response to the news to close at $15.64 per share on July 16, 2020.

80. Although the notification may not have specified the deficiencies, Tricida and Klaerner knew the deficiencies the FDA had been raising for years. Indeed, they—better than anyone—knew the shortcomings of the veverimer trials. The second quarter 2020 Form 10-Q, filed August 6, 2020, finally disclosed some of the deficiencies:

> In our late cycle meeting with the FDA, held in May 2020, we addressed two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population.

In the same 10-Q, the Company finally conceded that "we are likely to receive … a Complete Response Letter, or CRL."

81. During an August 5, 2020, earnings call, an analyst demonstrated how even experts in the market had been misled into believing that Tricida had secured the FDA's cooperation, asking Klaerner to "remind us of the process that you went through to get the FDA to sign off on the design of the pivotal study and in particular, the serum bicarbonate primary endpoint. Was there any disagreement between you and the FDA in the design? Or are you both on the same page?" Klaerner offered a carefully worded response, stating the Company had reached agreement with the FDA (1) "that we are treating a serious disease, that there is an unmet medical need and that we have a surrogate that's likely going to translate to clinical benefit," and (2) on "a quantitative understanding … of how the surrogate really impacts … the progression of kidney disease." Based on those agreements, said Klaerner, Tricida designed the TRCA-301/TRCA-301E and VALOR-CKD trials.

82. On August 24, 2020, Tricida announced that it had received the anticipated CRL and revealed that the FDA's concerns were, in fact, the very issues the FDA had raised in advance of the late cycle meeting in May 2020 (and which Tricida had always known, but never disclosed to the market). Klaerner was quoted as saying "we are pleased that the FDA has provided helpful, specific comments and indicated their willingness to continue to work with us to pursue approval of veverimer." The Company also said it would request a Type A meeting with the FDA to discuss next steps.

83. The contents of the CRL were not disclosed to the market. [redacted]

85. On September 21, 2020, Tricida formally requested a Type A meeting with the FDA. [redacted]

86. On October 29, 2020, Tricida provided an update to investors on the Type A meeting. Tricida proposed conducting an interim analysis of data from about 500 patients in the VALOR-CKD trial, hoping that it would allow the Company to resubmit its NDA "within a matter of months," but the FDA rejected the proposal. "Based on feedback during the Type A meeting,"

Tricida revealed that it "now believes the FDA will also require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program and that the FDA is unlikely to rely solely on serum bicarbonate data for determination of efficacy."

87. During an analyst call the same day, Klaerner acknowledged for the first time that the TRCA-301/TRCA-301E trials failed to enroll enough subjects who were representative of the U.S. patient population. Describing future enrollment in the VALOR-CKD trial, Klaerner said, "We are focusing on U.S. and Western Europe and Canada to get more patients from those regions, *even though we think that patients are pretty much the same all over the world*, but it does make sense to add in a few more from those more U.S.-like countries. And FDA asked us to do that." (Emphasis added).

88. The stock price took another hit on this news, falling from a closing price of $8.27 per share on October 28, 2020, to close at $4.37 per share on October 29, 2020.

89. On December 8, 2020, Tricida announced that it had revised the protocol for its VALOR-CKD trial, switching from "an adaptive design" with "an unblinded interim analysis for sample size re-estimation" to "a group sequential design, no interim analysis for sample size adjustment, and unblinded interim analyses for early stopping for efficacy after 150 primary endpoint events … and 250 primary endpoint events … have accrued." Despite having repeatedly stated its commitment to fully enrolling or nearly fully enrolling the VALOR-CKD trial prior to NDA submission, Tricida revised the expected date by which enrollment would be completed to the end of 2022.

90. Tricida submitted a Formal Dispute Resolution Request just a few days earlier, on December 3, 2020, in a final attempt to convince the FDA that the magnitude and durability of serum bicarbonate change seen in the TRCA-301/TRCA-301E trial was reasonably likely to predict clinical benefit in the treatment of CKD.

91. On February 17, 2021, Tricida received an Appeal Denied Letter ("ADL") from the FDA's Office of New Drugs ("OND"). OND cited to its prior communications with Tricida in

explaining that it had consistently maintained that the treatment effect on serum bicarbonate would have to be of sufficient magnitude to justify approval:

> In addition to the limitations of Study TRCA-301/-301E leading to the determination that there was not substantial evidence of effectiveness based upon this single trial, the Division also concluded that the extent of effect on SBC observed was not "reasonably likely" to predict benefit on CKD progression. In earlier meetings you had with the Division, the Division expressed skepticism that SBC was an acceptable surrogate for delay of CKD progression. For example, the Division commented that "...we do not agree that the submitted data are sufficient to support the use of serum bicarbonate concentrations as a surrogate endpoint for a treatment effect on renal, bone, and/or muscle function-related outcomes in the proposed population." (Meeting Minutes 12/23/2016). In a subsequent meeting, the Division ultimately did agree that SBC may be a reasonably likely surrogate ***but noted that "a key issue is whether the magnitude of the treatment effect on serum bicarbonate....is sufficient to provide confidence that the treatment will have the anticipated benefit..."***. (Meeting Minutes, 3/9/17). The Division went on to point out that the way to assess this was to assure that the confirmatory trial was powered to see the anticipated effect size on CKD progression.
>
> * * *
>
> You note that the 5.5 mEq/L increase relative to placebo predicts a 32% relative risk reduction in the CKD composite. You then state that "the Division's suggestion that any benefit short of this would be seen as unacceptably modest is not defensible." (Page 27, FDRR letter). ***As I have already noted, this misrepresents the concern expressed in the CR letter—that the relatively small increase in SBC with TRC101 may not provide a discernible reduction in CKD progression***. . . . ***this perspective is entirely consistent with prior advice from the Division***—as I noted already. That is, the increment in SBC with TRC101 in Study TRCA-301/-301E does not meet the "test" advised by the Division—that the size of the increase in SBC should be anticipated to translate to a reduction in the renal composite endpoint for which the confirmatory study is powered (meeting minutes 3/9/17, quoted above).

(Emphasis added).

92. On February 25, 2021, Tricida disclosed its receipt of the ADL and shared the basis for the OND's rejection of the veverimer NDA:

> In the ADL, the OND acknowledged that the TRCA-301/TRCA-301E trial met its serum bicarbonate endpoints with statistical significance but concluded that the extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a

> discernible reduction in CKD progression. The OND also concluded that the confirmatory trial, VALOR CKD, is underpowered to detect the effect size (13%) predicted by the original Tangri model (also known as the Predictive MA Model) based upon the placebo-subtracted mean treatment effect observed in the TRCA-301/TRCA-301E trial.
>
> The OND also provided feedback on other concerns that are particularly relevant in an NDA supported by a single registrational trial. The OND noted concerns around the trial results being strongly influenced by a single site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population.

93. Tricida's stock price took another hit as investors responded to this news, falling from a close of $7.36 per share on February 25, 2021, to close at $5.11 per share on February 26, 2021.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

Pre-Class Period Statements

94. On June 5, 2018, Tricida issued a press release titled "Tricida Announces Positive Pivotal Phase 3 Clinical Trial Results for TRC101 in CKD Patients with Metabolic Acidosis." The press release stated, in pertinent part,

> Tricida, Inc., a late-stage pharmaceutical company, announced results from *its pivotal Phase 3 double-blind, randomized, placebo-controlled, multi-center Phase 3 clinical trial, TRCA-301*, in 217 chronic kidney disease (CKD) patients with metabolic acidosis. TRC101 represents a first-in-class candidate for the treatment of metabolic acidosis, a common complication of CKD that can accelerate progression of kidney disease, increase the risk of muscle wasting and cause the loss of bone density.
>
> Based on the initial topline analyses, *the TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner* ($p < 0.0001$ for all primary and secondary endpoints). TRC101 was well tolerated in the TRCA-301 trial. Both active (124 subjects) and placebo groups (93 subjects) had low discontinuation rates and low rates of treatment-related adverse events.
>
> * * *
>
> *The TRCA-301 double-blind, randomized, placebo-controlled Phase 3 trial was conducted at 47 sites in the United States and Europe* and enrolled 217

> Stage 3b or 4 CKD patients with baseline blood bicarbonate levels between 12 mEq/L and 20 mEq/L. Subjects were randomized in a 4:3 ratio to receive TRC101 or placebo. The study drug dosing (TRC101 or placebo) continued for 12 weeks once daily. The primary outcome measure was change from baseline in blood bicarbonate (Time Frame: Week 12) and included comparison of TRC101 and placebo with regard to the proportions of subjects with change from baseline in blood bicarbonate ≥ 4 mEq/L or with blood bicarbonate in the normal range (22 to 29 mEq/L). Eligible subjects that completed the TRCA-301 trial were invited to participate in a 40-week safety extension trial, TRCA-301E. *Of the 208 subjects who completed the TRCA-301 trial, 196 were enrolled in the TRCA-301E safety extension trial.*
>
> * * *
>
> Tricida, Inc., is a late-stage pharmaceutical company focused on the development and commercialization of TRC101, a non-absorbed, orally-dosed polymer drug designed to treat metabolic acidosis in patients with chronic kidney disease. The results of the pivotal Phase 3 clinical trial reported today, along with results from a successful double-blind, randomized, placebo-controlled Phase 1/2 trial and an ongoing safety extension trial, TRCA-301E, are intended to serve as the basis for the submission of a U.S. New Drug Application (NDA) for TRC101 under the Accelerated Approval Program of the U.S. Food and Drug Administration (FDA).

95. The statements identified in italics above were false and misleading. The statement that TRCA-301 was a "multi-center" trial "conducted at 47 sites in the United States and Europe" was materially false and misleading when made for two reasons, and Defendants knew or recklessly disregarded the truth in making the statement. First, most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, and second, [redacted] both material pieces of information for an investor to be able to accurately assess the likelihood that veverimer would receive FDA approval. The omission of these facts was material and stating that the TRCA-301 trial was "multi-center" and conducted "at 47 sites in the United States and Europe" was materially misleading.

96. Demonstrating that a pivotal trial is adequate and well controlled under 21 C.F.R. § 314.126 requires showing that any foreign data are applicable to the U.S. population and U.S. medical practice. F FDA, *Guidance for Industry and FDA Staff, FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions* 9 (March 2012),

https://www.fda.gov/media/83209/download; *see also* Nancy J. Stark, *Clinical Studies: Europe or the United States?*, Medical Device & Diagnostic Industry (May 1, 2004), https://www.mddionline.com/news/clinical-studies-europe-or-united-states ("FDA's most common objection to European data is related to how representative European subjects are of the U.S. patient population."). But "geographic, socio-economic, infrastructure, cultural and educational features" of "the Eastern European nephrology community" mean that "[s]everal aspects of CKD differ significantly" compared with Western Europe, which is generally considered to be the most U.S.-like foreign region besides Canada. Mehmet Sukru Sever, et. al., *A Roadmap for Optimizing Chronic Kidney Disease Patient Care and Patient-Oriented Research in the Eastern European Nephrology Community*, Clinical Kidney J. (Dec. 22, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7857792/. Thus, the fact that a majority of trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, raised the risk that trial participants would not be sufficiently representative of the U.S. patient population and U.S. medical practice for the FDA to accept the trial results. This, in turn, was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval. Accordingly, the omission of the fact that a majority of trial sites for the Phase 3 trial were in Eastern Europe from the statement that the TRCA-301 trial was conducted "at 47 sites in the United States and Europe" rendered it false and misleading.

97. Tricida and Klaerner knew that this omission made the statement about Tricida's Phase 3 trial having been conducted "at 47 sites in the United States and Europe" false and misleading because the FDA specifically raised the issue with Tricida. [redacted]

[redacted] Tricida and Klaerner knew, or recklessly disregarded, that the FDA would carefully and critically consider *where* the patients who made up TRCA-301 were located. Despite this, [redacted]

98. Given that Tricida intended to submit an NDA predicated upon only a single pivotal Phase 3 trial, Tricida and Klaerner knew that the TRCA-301/TRCA-301E trial would receive enhanced scrutiny from the FDA. Indeed, FDA guidance makes clear that "[a] conclusion based on two persuasive studies will always be more secure than a conclusion based on a single, comparably persuasive study." FDA, *Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* 13 (May 1998), https://www.fda.gov/media/71655/download. "For this reason, reliance on only a single study will generally be limited to situations in which a trial has demonstrated a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible." *Id.* One of the characteristics the FDA looks for in a single study capable of supporting an effectiveness claim is "a large multicenter study in which (1) no single study site provided an unusually large fraction of the patients and (2) no single investigator or site was disproportionately responsible for the favorable effect seen." *Id.* Tricida and Klaerner knew the patient enrollment details for its own study, and they knew that data from one high-enrolling clinical site, [redacted], had a disproportionate impact on the trial's results. [redacted]. Tricida and Klaerner knew, or recklessly disregarded, that patients disproportionately enrolled in one trial site undermined the so-called "randomness" of the trial and undermined its credibility with the FDA. This information was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval. The omission of

this information from the statement that the Phase 3 trial was "multi-center" and "conducted at 47 sites" rendered it materially false and misleading.

99. It was also misleading to tout that TRCA-301 "met both its primary and secondary endpoints in a highly statistically significant manner" [redacted]

100. Tricida's statement that TRCA-301 had "met both its primary and secondary endpoints in a highly statistically significant manner" was further misleading [redacted]

[redacted]

Materially False and Misleading Statements and Omissions Concerning the IPO

101. On June 27, 2018, Tricida filed a Form S-1/A and related Rule 424(b)(4) Prospectus in connection with the Company's IPO ("2018 Prospectus"), both of which were signed by Defendant Klaerner. Under "Our Development Program for TRC101," the 2018 Prospectus stated,

> In May 2018, we completed our pivotal Phase 3 clinical trial, TRCA-301. The double blind, randomized, placebo-controlled trial enrolled 217 subjects with Stage 3b or 4 CKD (an estimated glomerular filtration rate, or eGFR, of 20 to 40 mL/min/1.73m2) and low blood bicarbonate levels (between 12 mEq/L and 20 mEq/L).
>
> * * *
>
> *We conducted the trial at 47 sites in the United States and Europe.*

Under "Risk Disclosures," the 2018 Prospectus stated, "*We recently completed a* randomized, double-blind, placebo-controlled, *multicenter pivotal Phase 3 clinical trial for TRC101, known as TRCA-301.*"

102. For the reasons stated in ¶¶95-98, the statements identified in italics above were materially false and misleading and omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements. [redacted] it was misleading for Defendants to omit to reveal to investors that the vast majority of the patients came from Eastern Europe and that [redacted]

103. Established knowledge about foreign patient populations and FDA guidance aside, Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 2018 Prospectus cautioned that "the FDA may determine that

clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 2018 Prospectus warned at pages 10-11.

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

Not only were both statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients who are unlikely to be representative of the U.S. patient population and U.S. medical care, but they were misleading. As stated above and in ¶¶95-98, Tricida and Klaerner specifically knew the risks of using clinical data from a patient population outside the United States [redacted] Yet, Tricida and Klaerner omitted to reveal that the Phase 3 TRCA-301 trial was conducted using a patient population [redacted] from Eastern Europe—which the FDA does not consider to be applicable to a United States patient population under the circumstances—and that [redacted], making the risk disclosure not only ineffective but false and misleading.

104. The 2018 Prospectus further stated:

> Our development program for TRC101 is designed to obtain approval of TRC101 pursuant to the FDA's Accelerated Approval Program. Under the Accelerated Approval Program, we plan to pursue approval for TRC101 based upon efficacy data related to a primary endpoint measuring a change from baseline in blood bicarbonate level. We have completed a successful

> 135-subject, Phase 1/2 trial, TRCA-101, and a 217-subject, pivotal Phase 3 clinical trial, TRCA-301. Eligible subjects who completed the 12-week treatment period in our pivotal TRCA-301 trial were invited to continue in our 40-week safety extension trial, TRCA-301E, which we expect to complete in the first half of 2019. *Based on feedback from the FDA, we believe that the data from the TRCA-101, TRCA-301 and TRCA-301E trials will provide sufficient evidence of clinical safety and efficacy to support the submission and review of an NDA for TRC101 pursuant to the Accelerated Approval Program.* We plan to submit an NDA for TRC101 in the second half of 2019.

In addition to the reasons explained above in ¶¶99, 100, the statement identified in italics above was false and misleading, or omitted to disclose material facts necessary to keep it from being misleading, because [redacted]

105. Accordingly, it was materially false and misleading for Defendants to state that the FDA's "feedback" indicated that data from TRCA-301 sufficiently supported accelerated approval while failing to disclose [redacted] Defendants also had no reasonable basis to believe that the data from TRCA-301 was sufficient to support accelerated approval as [redacted]

106. The 2018 Prospectus also stated:

> *The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner* ($p < 0.0001$ for all primary and secondary endpoints). TRC101 was well tolerated in our TRCA-301 trial. Both active (124 subjects) and placebo groups (93 subjects) had low discontinuation rates and low rates of treatment-related adverse events.

* * *

Initial topline analysis of our pivotal Phase 3 clinical trial, TRCA-301, indicates that treatment with TRC101 resulted in statistically significant increases in blood bicarbonate, meeting both the primary and secondary endpoints of the trial. After 12 weeks of treatment, 59.2% of subjects in the TRC101-treated group, compared with 22.5% of subjects in the placebo group, exhibited an increase in blood bicarbonate level of at least 4 mEq/L or achieved a blood bicarbonate level in the normal range of 22 to 29 mEq/L, which was the primary endpoint of the trial. The secondary endpoint of the trial, the mean change in blood bicarbonate from baseline to week 12, was 4.49 mEq/L in the TRC101-treated group, compared with 1.66 mEq/L in the placebo group. The results of the primary and secondary endpoints were highly statistically significant ($p < 0.0001$).

107. For the reasons stated in ¶¶99, 100, the statements identified in italicsabove were materially false and misleading and omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements. [redacted]

108. Both the 2018 Prospectus and the Prospectus accompanying the April 2019 offering made the following additional statements regarding the endpoints and magnitude of the treatment effect:

> Because we are developing a product candidate for the treatment of a disease or condition ***on the basis of an unvalidated surrogate endpoint, there are increased risks that the FDA or other regulatory authorities may find that our clinical program provides insufficient evidence of clinical benefit***, may have difficulty analyzing and interpreting the results of our clinical program, and may delay or refuse to approve TRC101.
>
> In addition, we are not aware of any chronic therapeutic agent that has previously been approved by the FDA on the basis of a clinical trial that used blood bicarbonate level as the primary endpoint. We have engaged in discussions with the FDA regarding the design of our pivotal Phase 3 clinical trial, TRCA-301, and whether the use of blood bicarbonate as a surrogate endpoint is reasonably likely to predict clinical benefit. However, the FDA has discretion at any time, including during the NDA review, to determine whether there is support for the use of blood bicarbonate as a surrogate endpoint.

> ***Key issues with our endpoint include uncertainty about the degree of change from baseline blood bicarbonate that will translate into improved clinical outcomes, the population in which such change is expected to translate into improved clinical outcomes, and the need for data supporting a causal relationship between blood bicarbonate concentration and clinical outcomes. As a result, we cannot be certain that FDA will ultimately conclude that the design and results of our pivotal Phase 3 clinical trial, TRCA-301, which uses changes from baseline in blood bicarbonate level as the primary endpoint, will be sufficient for approval of TRC101.***
>
> Moreover, even if the FDA does find that changes from baseline in blood bicarbonate are sufficiently likely to predict clinical benefit for patients, ***the FDA may not agree that we have achieved the primary endpoint in our pivotal Phase 3 clinical trial, TRCA-301, to the magnitude or to the degree of statistical significance required by the FDA***. Further, even if those requirements are satisfied, the FDA also could give overriding weight to inconsistent or otherwise confounding results on other efficacy endpoints or other results of the trial, including results on secondary and exploratory endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Regulatory authorities in other countries may take similar positions.

For the reasons stated in ¶¶99, 100, the statements identified in italics above were too generalized to actually disclaim the specific issues repeatedly raised to Tricida and Klearner by the FDA. The statements were materially false and misleading and omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements. As stated in ¶¶23, 47-50, Tricida and Klaerner knew [redacted]

Materially False and Misleading Statements and Omissions Concerning the Second and Third Quarters of 2018

109. On August 9, 2018, Tricida filed its Form 10-Q for the second quarter of 2018, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 2Q18 10-Q,

pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

110. On November 8, 2018, Tricida filed its Form 10-Q for the third quarter of 2018, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 2Q18 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

111. The risk disclosures in both the 2Q18 10-Q and 3Q18 10-Q stated,

> *We recently completed a* randomized, double-blind, placebo-controlled, *multicenter pivotal Phase 3 clinical trial for TRC101, known as TRCA-301.* The TRCA-301 trial enrolled 217 CKD patients with metabolic acidosis. Eligible subjects who completed the 12-week treatment period in our pivotal Phase 3 trial were invited to continue in our 40-week safety extension trial, TRCA-301E.
>
> * * *
>
> *Our safety extension trial, TRCA-301E, is being conducted at 29 sites in the United States and Europe.*

112. For the reasons stated in ¶¶95-98, the statements identified in italics above were materially false and misleading and omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements. [redacted] it was misleading for Defendants to omit to reveal to investors that the vast majority of the patients came from Eastern Europe.

113. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 10-Qs cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and

efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Qs warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, these italicized statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients who are unlikely to be representative of the U.S. patient population and U.S. medical care, and were materially misleading. As stated above, Tricida and Klaerner knew the risks of using clinical data from a patient population outside the United States because [redacted] Additionally, the extension trial, TRCA-301E, was even less representative of the U.S. population than the 12-week TRCA-301. [redacted]

Materially False and Misleading Statements and Omissions Concerning the Full Year 2018 and the Second Public Offering

114. On March 28, 2019, Tricida held an earnings call. Klaerner reported on the call that Tricida had the results of the TRCA-301E extension trial, and that the combined results of the

TRCA-301/TRCA-301E trial "far exceeded our expectations." Not only did the extension trial "me[e]t its primary and all secondary endpoints," but "we have observed evidence of clinical benefit in TRC101-treated subjects, including reduced all-cause mortality, slowing of CKD progression and improved physical function." Klaerner stated: "we feel good about what we've learned in the 301E study regarding safety and efficacy, increasing our confidence for a successful VALOR-CKD trial."

115. The statements Klaerner made on the March 28, 2019 earnings call identified above were false and misleading, and omitted to disclose material information necessary to make them not misleading. As explained above in ¶¶99, 100, [redacted]

116. On March 29, 2019, Tricida filed its Form 10-K for the full year 2018, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 2018 10-K, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Annual Report on Form 10-K of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

117. On April 3, 2019, Tricida filed a Form S-1MEF and related Rule 424(b)(4) Prospectus in connection with the Company's secondary offering, both of which were signed by Defendant Klaerner (the "2019 Prospectus").

118. The "Business" section of the 2018 10-K and 2019 Prospectus stated, "In May 2018, we completed our pivotal Phase 3 clinical trial, TRCA-301, and in March 2019, the results of this trial were published in The Lancet.... *We conducted the trial at 47 sites in the United States and Europe*, of which 37 sites enrolled patients." The risk disclosures in the 2018 10-K and April 2019 Prospectus stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for TRC101, known as TRCA-301.... *Our extension trial, TRCA-301E, was conducted at 37 sites in the United States and Europe.*"

119. For the reasons stated in ¶¶95-98, the statements identified in italics above were materially false and misleading and omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements. [redacted], it was misleading for Defendants to omit to reveal to investors that the vast majority of the patients came from Eastern Europe.

120. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 2018 10-K and 2019 Prospectus cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-K and 2019 Prospectus warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, these italicized statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients who are unlikely to be representative of the U.S. patient population and U.S. medical care, and Defendants omitted material facts necessary to keep them from being misleading.

121. The 2018 10-K also stated:

> In May 2018, we completed our randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial, TRCA-301, in 217 CKD patients with metabolic acidosis, and in March 2019, the results of this trial were published in The Lancet. *The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner (p<0.0001 for both the primary and secondary endpoints).* TRC101 was well tolerated in our TRCA-301 trial. One hundred ninety-six of the 208 eligible subjects who completed the 12-week treatment period in our pivotal TRCA-301 trial agreed to continue into our 40-week blinded extension trial, TRCA-301E.

122. For the reasons stated in ¶¶99, 100, the statements italicized above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading. It was misleading to characterize TRCA-301 as having "met both its primary and secondary endpoints in a highly statistically significant manner" without disclosing that [redacted]

123. The 2019 Prospectus stated:

> In May 2018, we completed our randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial, TRCA-301, in 217 CKD patients with metabolic acidosis, and in March 2019, the results of this trial were published in The Lancet. ***The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner (p<0.0001 for both the primary and secondary endpoints).*** TRC101 was well tolerated in our TRCA-301 trial. One hundred ninety-six of the 208 eligible subjects who completed the 12-week treatment period in our pivotal TRCA-301 trial agreed to continue into our 40-week blinded extension trial, TRCA-301E.
>
> ***In March 2019, we completed our TRCA-301E trial. Based on the initial topline data analyses, the TRCA-301E trial met its primary and all secondary endpoints. We believe these results provide evidence of long-term safety and tolerability of TRC101 and durability of blood bicarbonate effect.*** The placebo-adjusted improvements in favor of TRC101-treated subjects in the two measures of physical function at Week 52 approximately doubled compared to the results at Week 12 observed in the parent trial, TRCA-301. We believe the results from these two assessments provide consistent evidence of a clinically meaningful improvement in physical function and related aspects of quality of life for TRC101-treated subjects.

> The statistical analysis plan for the TRCA-301E trial also specified a comparison of the TRC101 and placebo groups for the time to the composite clinical endpoint of death (all-cause mortality), dialysis/kidney transplant (renal replacement therapy) or a ≥50% decline in estimated glomerular filtration rate (eGFR), taken together DD50. Over the combined (TRCA-301 and TRCA-301E trials) 52-week treatment period, DD50 was prolonged in the TRC101 group compared to the placebo group, with an annualized DD50 incidence rate, calculated as 100 times the number of events divided by the total person-years, of 4.2% in the TRC101 group vs 12.0% in the placebo group (p = 0.0224).

For the reasons stated in ¶¶99, 100, the statements italicized above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading. It was misleading to state that "we believe these results provide evidence of long-term safety and tolerability of TRC101 and durability of blood bicarbonate effect" without disclosing that [redacted]

Materially False and Misleading Statements and Omissions Concerning First Quarter of 2019

124. On May 10, 2019, Tricida filed its Form 10-Q for the first quarter of 2019, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 1Q19 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

125. The 1Q19 10Q stated,

> In May 2018, we completed our randomized, double-blind, placebo controlled, pivotal Phase 3 clinical trial, TRCA-301, in 217 CKD patients with metabolic acidosis. *The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner* (p < 0.0001 for both the primary and secondary endpoints). *One hundred ninety-six of the 208 subjects who completed the 12-week treatment period in our pivotal Phase 3 trial, TRCA-301, agreed and were eligible to continue in our extension trial,* TRCA-301E, which we completed in March 2019.

126. For the reasons stated in ¶¶99, 100, the statements identified in italics above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading. As stated above, it was misleading to characterize TRCA-301 as having "met both its primary and secondary endpoints in a highly statistically significant manner" without disclosing that [redacted]

127. It was also misleading to tout that 196 out of 208 subjects who completed the 12-week TRCA-301 trial continued on to the 40-week TRCA-301E extension when [redacted]

128. The risk disclosures in the 1Q19 10-Q stated,

> In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301.
>
> * * *
>
> Our 40-week extension trial, TRCA-301E, *was conducted at 37 sites in the United States and Europe*.

129. For the reasons stated in ¶¶95-98, the statements identified in italics above were false and misleading, omitted material information, and Defendants knew or recklessly disregarded the truth in making these statements.

130. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 1Q19 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials

> should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, these italicized statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients [redacted], and Defendants omitted material facts necessary to keep them from being misleading.

Materially False and Misleading Statements and Omissions at the Goldman Sachs Global Healthcare Conference

131. On June 12, 2019, Defendant Klaerner spoke at the Goldman Sachs Global Healthcare Conference:

> Graig Suvannavejh Goldman Sachs Group Inc., Research Division – Executive Director & Senior Equity Research Analyst:
>
> I think it's fascinating. So veverimer is your lead program. And it's -- how would you describe what's unique about that? And maybe that transition to kind of the clinical data that you've generated for that program?
>
> Gerrit Klaerner Tricida, Inc. – Founder, President, CEO & Executive Director:
>
> Yes. Let's start with the most recent news, which, in my career, I've never experienced. We set out to do a 1-year extension study, where we hope to see good safety, which we did. We hoped to see continued durable effect of our surrogate marker, which is basically the increase of serum bicarbonate. And on top of it, in this blinded placebo-controlled study, we actually saw a reduced all-cause mortality, reduced number of patients requiring dialysis and fewer patients having -- losing 50% of the kidney function.

> And when you fast-forward in all the work that we've done, from a discovery to an early development, to a late stage development, ***agreeing with FDA, an accelerated approval path, you*** -- *all you expect to do is to show a surrogate effect, and then you have a post-marketing commitment that ultimately then, you confirm that, that surrogate is going to translate.*
>
> Now we found ourselves with 1-year safety extension data that showed clinical benefit. And I think that excitement, you can feel now, I think, in the company, both from interacting with payers, interacting with physicians, interacting with regulators, I think that is a good thing to have.

132. For the reasons stated in ¶¶99, 100, the statements identified in italics above were false and misleading, or omitted to disclose material information necessary to prevent them from being misleading. Klaerner knew these statements to be false and misleading or was reckless is his disregard for the truth when he made them.

133. Additionally, Klaerner materially misrepresented that Tricida had reached agreement with the FDA regarding TRCA-301's and TRCA-301E's endpoints. [redacted]

Materially False and Misleading Statements and Omissions Concerning the Second Quarter of 2019

134. On August 9, 2019, Tricida filed its Form 10-Q for the second quarter of 2019, which was signed by Defendant Klaerner.

135. Klaerner certified in Exhibit 31.1 to the 2Q19 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the

circumstances under which such statements were made, not misleading with respect to the period covered by this report."

136. The August 9, 2019 10-Q stated:

> In May 2018, we completed our randomized, double-blind, placebo controlled, pivotal Phase 3 clinical trial, TRCA-301, in 217 CKD patients with metabolic acidosis. *The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner* ($p < 0.0001$ for both the primary and secondary endpoints). *One hundred ninety-six of the 208 subjects who completed the 12-week treatment period in our TRCA-301 trial* agreed *and were eligible to continue in our 40-week extension trial, TRCA-301E, which we completed in March 2019*. The TRCA-301E trial met its primary and all secondary endpoints.

137. For the reasons stated in ¶¶99, 100, the statements identified in italics above were false and misleading and omitted to disclose material facts necessary to keep them from being misleading. It was misleading to characterize TRCA-301 as having "met both its primary and secondary endpoints in a highly statistically significant manner" without disclosing that [redacted]

138. As stated above in ¶127, it was also misleading to tout that 196 out of 208 subjects who completed the 12-week TRCA-301 trial continued on to the 40-week TRCA-301E extension. [redacted]

139. The risk disclosures in the 2Q19 10-Q stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301.... Our 40-week extension trial, TRCA-301E, *was conducted at 37 sites in the United States and Europe*."

140. The statements identified in italics above were false and misleading, and omitted material information. In addition to the reasons explained above in ¶¶95-98, [redacted]

[redacted]

141. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 2Q19 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, 140, these italicized statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients [redacted], and Defendants omitted material facts necessary to keep them from being misleading.

Materially False and Misleading Statements and Omissions Concerning the Third Quarter of 2019

142. On November 14, 2019, Tricida filed its Form 10-Q for the third quarter of 2019, which was signed by Defendant Klaerner.

143. Klaerner certified in Exhibit 31.1 to the 3Q19 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

144. The November 14, 2019 10-Q stated:

> In May 2018, we completed our randomized, double-blind, placebo controlled, pivotal Phase 3 clinical trial, TRCA-301, in 217 CKD patients with metabolic acidosis. *The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner* ($p < 0.0001$ for both the primary and secondary endpoints). *One hundred ninety-six of the 208 subjects who completed the 12-week treatment period in our TRCA-301 trial agreed and were eligible to continue in our 40-week extension trial,* TRCA-301E, which we completed in March 2019. The TRCA-301E trial met its primary and all secondary endpoints.

145. For the reasons stated in ¶¶99, 100, 127, the statements identified in italics above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading.

146. The risk disclosures in the 3Q19 10-Q stated,

> In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301.
>
> * * *
>
> *Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe*.

147. For the reasons stated in ¶¶95-98, 140, the statements identified in italics above were false and misleading, or omitted to disclose material facts necessary to keep them from being

misleading. As stated above, Tricida and Klaerner knew, or recklessly disregarded, that characterizing the trials as being conducted in "the United States and Europe" was false and misleading because [redacted].

148. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 3Q19 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, 140, these italicized statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients [redacted], and Defendants omitted material facts necessary to keep them from being misleading.

Materially False and Misleading Statements and Omissions Concerning the Fourth Quarter and Year 2019

149. On March 2, 2020, Tricida filed its Form 10-K for the year 2019, which was signed by Defendant Klaerner.

150. Klaerner certified in Exhibit 31.1 to the 2019 10-K, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Annual Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

151. The "Business" section of the 10-K stated,

> *We conducted the [TRCA-301] trial at 47 sites in the United States and Europe*, of which 37 sites enrolled patients.
>
> * * *
>
> *Based on the magnitude of the increase in serum bicarbonate observed in our pivotal Phase 3 trial, TRCA-301, and the inverse relationship between serum bicarbonate and risk of renal events described by the Predictive MA Model, we have determined that randomizing 1,600 subjects* to veverimer or placebo in a 1:1 ratio will result in 90% power to show a 30% to 35% reduction in renal events in the VALOR-CKD trial.

152. The risk disclosures stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301…. *Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe.*"

153. In addition to the reasons stated in ¶¶95-98, 140, the statements identified in italics above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading. [redacted]

[redacted]

154. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 2019 10-K cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-K warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, 140, 153, these italicized statements were too generalized to disclaim the specific risk at issue but demonstrate Defendants' knowledge of the specific risk and were actually false and misleading. [redacted]

[redacted]

155. The 2019 10-K also contained false and misleading statements about the Phase 3 trial's results, specifically about the trial having met its primary and secondary endpoints:

> The TRCA-301 trial was a double-blind, placebo-controlled trial that randomized 217 patients with non-dialysis dependent CKD and metabolic acidosis. ***The trial met both its primary and secondary endpoints in a highly statistically significant manner (p<0.0001 for both the primary and secondary endpoints).*** Veverimer was well tolerated in our TRCA-301 trial. The primary endpoint of the trial measured improvements in serum bicarbonate levels in veverimer-treated patients versus placebo. Serum bicarbonate is a surrogate measure of metabolic acidosis and a persistent serum bicarbonate level below 22 mEq/L indicates metabolic acidosis. ***After 12 weeks of treatment, 59.2% of subjects in the veverimer-treated group, compared with 22.5% of subjects in the placebo group, had an increase in serum bicarbonate level of at least 4 mEq/L or achieved a serum bicarbonate level in the normal range of 22 to 29 mEq/L, which was the primary endpoint of the trial. The secondary endpoint of the trial, the least squares, or LS, mean change from baseline to week 12 in serum bicarbonate, was 4.42 mEq/L in the veverimer-treated group, compared with 1.78 mEq/L in the placebo group. The mean change in serum bicarbonate from baseline to week 12 was 4.5 mEq/L in the veverimer-treated group, compared with 1.7 mEq/L in the placebo group.***

156. The statements identified above in italics were false and misleading because they misrepresented veverimer's true chances of approval based on the results of the Phase 3 trial and omitted core issues with the trial's efficacy endpoints, as described above in ¶¶99, 100, 127. [redacted]

[redacted]

[redacted]

157. The 2019 10-K also stated that "We believe that the data from the TRCA-101, TRCA-301 and TRCA-301E clinical trials will provide sufficient clinical evidence of safety and efficacy to support the approval of our NDA for vevcrimer pursuant to the Accelerated Approval Program." In addition to the reasons stated in ¶¶99, 100, 127, this statement was false and misleading, and omitted material information, for failing to disclose the "Significant Issue" of the magnitude of the treatment effect on blood bicarbonate and the ability of TRCA-303 to confirm a treatment benefit, as stated by the FDA to Tricida on January 27, 2020. Neither Tricida nor Klaerner could reasonably have believed that the data from the clinical trials would provide sufficient clinical evidence of safety and efficacy to support an NDA after the specific negative feedback they received from the FDA at the January 27, 2020 mid-cycle meeting.

Materially False and Misleading Statements and Omissions Concerning the First Quarter of 2020

158. On May 7, 2020, Tricida held its 1Q20 earnings call with analysts. During the call, Klaerner stated,

> In our Day 74 letter, *the FDA indicated that they plan to hold an advisory committee meeting or AdCom to discuss the application. In our late-cycle meeting with the FDA held in May 2020, the FDA indicated it currently does not plan to hold an AdCom to discuss vevcrimer due in part to the logistical challenges posed by COVID-19. In our late-cycle meeting with FDA, we took the opportunity to address outstanding review issues.* We presented our data and rationale as to *why we think we very much satisfied the requirements for initial approval under the Accelerated Approval Program including the magnitude and durability of the treatment effect on the surrogate markup serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials.*
>
> Under the initial approval, *we have to ensure that US patients who would be prescribed vevcrimer get clinically significant benefit that outweighs the risk of treatment. Overall, while the FDA continues its review, we remain*

confident that our submission meets the standard for approval through the Accelerated Approval Program.

159. The statements identified in italics above were false and misleading. Klaerner made multiple false and misleading statements on the May 7, 2020 conference call by failing to disclose material information necessary to render the statements true in the context in which they were made. First, the reason why the FDA "indicated it currently does not plan to hold an AdCom to discuss veverimer" was not due to the "logistical challenges posed by COVID-19," [redacted] Klaerner therefore knew, or recklessly disregarded, that there would be no AdCom meeting because of the significant issues with Tricida's application of Accelerated Approval.

160. It was also misleading for Klaerner to state that he was "confident" that Tricida's "submission me[t] the standard for approval through the Accelerated Approval Program" [redacted]

161. It was further misleading for Klaerner to state that Tricida had satisfied the requirements for Accelerated Approval by demonstrating a treatment effect on SBC of sufficient "magnitude and durability" [redacted]

[redacted]

162. Plus, by discussing the data underling the clinical trial and the "outstanding clinical review issues" Klaener misled investors by omitting to reveal [redacted], as stated in ¶¶95-98, 140, 153. Tricida confirmed as much in its 2Q20 10-Q, filed August 6, 2020, in which the Company disclosed,

> In our late cycle meeting with the FDA, held in May 2020, we addressed two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population.

[redacted]. Given the magnitude of these issues, the Company said in the 2Q20 10-Q that it was likely to receive a CRL. These review issues proved to be the main reasons for the FDA's rejection of veverimer, as the Company finally spelled out in a February 25, 2021, press release titled "Tricida Has Received an Appeal Denied Letter from the Office of New Drugs of the FDA in Response to its Formal Dispute Resolution Request":

> In the ADL, the OND acknowledged that the TRCA-301/TRCA-301E trial met its serum bicarbonate endpoints with statistical significance but concluded that the extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression. The OND also concluded that the confirmatory trial, VALOR-CKD, is underpowered to detect the effect size (13%) predicted by the original Tangri model (also known as the Predictive MA Model) based upon the placebo-subtracted mean treatment effect observed in the TRCA-301/TRCA-301E trial.
>
> The OND also provided feedback on other concerns that are particularly relevant in an NDA supported by a single registrational trial. The OND noted concerns around the trial results being strongly influenced by a single

site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population.

163. Klaerner either knew, or recklessly disregarded, that these issues presented a significant obstacle to the approval of veverimer [redacted]

166. Klaerner's false statements were material because they concealed the true risk that the FDA would reject the veverimer NDA.

167. On May 8, 2020, Tricida filed its Form 10-Q for the first quarter of 2020, which was signed by Defendant Klaerner.

168. Klaerner certified in Exhibit 31.1 to the 1Q20 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

169. The risk disclosures section stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301.... *Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe.*"

170. For the reasons stated in ¶¶95-98, 140, 153, 165, the statements identified in italics above were false and misleading, or omitted to disclose material facts necessary to keep them from being misleading. As stated above, Tricida and Klaerner knew, or recklessly disregarded, that characterizing the trials as being conducted in "the United States and Europe" was misleading [redacted]

171. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 1Q20 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include*

> *differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.*
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶¶95-98, 140, 153, 165 these italicized statements were too generalized to disclaim the specific risk at issue but demonstrate Defendants' knowledge of the specific risk and were actually false and misleading. While the risk factors above characterized the risk of the FDA not accepting foreign data as a hypothetical (*e.g.*, "the FDA *may* not accept such foreign clinical data"), [redacted]. Stating that differences in clinical conditions and study populations "may" affect the acceptance of the foreign data was likewise misleading [redacted]

Materially False and Misleading Statements and Omissions Concerning Second Quarter 2020

172. On Augnst 5, 2020, after Tricida first disclosed limited information that the FDA had identified deficiencies with its NDA, Tricida held an earnings call earnings call to discuss its second quarter 2020 financial results. On the earnings call, an analyst asked Klaerner to "remind us of the process that you went through to get the FDA to sign off on the design of the pivotal study and in particular, the serum bicarbonate primary endpoint. Was there any disagreement between you and the FDA in the design? Or are you both on the same page?" Klaerner offered a carefully worded response, stating the Company had reached agreement with the FDA (1) "that we are treating a serious disease, that there is an unmet medical need and that we have a

surrogate that's likely going to translate to clinical benefit," and (2) on "a quantitative understanding … of how the surrogate really impacts … the progression of kidney disease." Based on those agreements, said Klaerner, Tricida designed the TRCA-301/TRCA-301E and VALOR-CKD trials.

173. Klaerner's response to the analyst's question was materially false and misleading for the reasons stated in ¶¶ 99, 100,127 157. [redacted] "quantitative understanding … of how the surrogate really impacts the progression of kidney disease."

THE TRUTH BEGINS TO EMERGE

174. On July 15, 2020, after the close of trading, Tricida issued a press release revealing that the FDA notified Tricida on July 14, 2020 that the Agency had "identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." Tricida said the notification did not "specify the deficiencies identified by the FDA," but "[t]he Company plans to work with the FDA to identify and seek to resolve the deficiencies." Klaerner was quoted in the press release, stating "We are surprised and disappointed by this news …. We continue to believe in the potential of veverimer to be disease modifying and our goal is to work with FDA to identify and resolve the issues in order to bring veverimer to patients."

175. In response to this news, the price of Tricida common stock fell $10.56 per share to close at $15.64 per share on July 16, 2020.

176. The July 15, 2020, press release publicly revealed for the first time that there were issues with the veverimer NDA, but Defendants still withheld material information from the investing public. Tricida and Klaerner were well aware of the deficiencies referenced by the FDA, i.e., that the majority of trial sites were in Eastern Europe and one site in particular was disproportionately responsible for the trial's enrollment, [redacted] Defendants had just met with the FDA in May 2020 for a late-cycle review, during which the FDA specifically raised concerns about the ability of the surrogate endpoint for the TRCA-301/TRCA-301E trial to demonstrate likely clinical

effect as well as the comparability of the trial subjects to the U.S. patient population and U.S. medical practice. Moreover, these had been long-standing points of discussion with the FDA throughout the clinical trials. And Defendants also knew that an NDA supported by a phase 3 program consisting of only a single pivotal trial, such as the veverimer NDA, would receive heightened scrutiny from the FDA. The press release indicated that the NDA would not be approved by the PDUFA date, but the details would have made clear that the NDA was nowhere near approval—i.e., it could not be salvaged by a short-term fix. The failure to mention these facts withheld key pieces of the whole truth.

177. On August 24, 2020, at 8:30 am, prior to the opening of trading, Tricida issued a press release announcing that it [had] received a Complete Response Letter ("CRL") from the FDA for its veverimer NDA on August 21, 2020:

> According to the CRL, the FDA is seeking additional data beyond the TRCA-301 and TRCA-301E trials regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and the applicability of the treatment effect to the U.S. population. FDA also expressed concern as to whether the demonstrated effect size would be reasonably likely to predict clinical benefit. There were no safety, clinical pharmacology/biopharmaceutics, CMC or non-clinical issues identified in the CRL.
>
> The CRL provided multiple options for resolving the identified deficiencies. In order to obtain approval for veverimer the company may or may not have to conduct an additional clinical trial. The FDA indicated it is willing to meet with Tricida to discuss options for obtaining approval, including under the Accelerated Approval Program.
>
> "We have collaborated with the FDA on the Accelerated Approval Program for veverimer and while we are disappointed to receive this CRL, we are pleased that the FDA has provided helpful, specific comments and indicated their willingness to continue to work with us to pursue approval of veverimer," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We remain confident in the fundamentals of, and unmet medical need for, veverimer and we continue to conduct our confirmatory trial, VALOR-CKD." Tricida plans to request a Type A meeting with the FDA in the coming weeks. A Type A meeting is usually scheduled within 30 days of the meeting request. Following the Type A meeting, anticipated early in the fourth quarter, Tricida plans to provide an update on next steps and estimated timing of a potential resubmission of the NDA.

178. Tricida's stock price fell by $3.13 per share, or 24% on this news, falling from its prior closing price of $13.24 per share to close at $10.11 per share on August 24, 2020.

179. The August 24, 2020, press release revealed for the first time the FDA's position that the Phase 3 TRCA-301/TRCA-301E trial was inadequate on its own to demonstrate the efficacy of veverimer. It also revealed that the FDA required additional data regarding the applicability of the observed treatment effect to the U.S. population. However, the press release went to great lengths to temper the true nature of these issues by suggesting that there were no severe obstacles to near-term approval and emphasizing (1) the "multiple options for resolving the identified deficiencies," (2) Klaerner's pleasure about the FDA's feedback, and (3) the Company's confidence in the "fundamentals" of veverimer, such that the VALOR-CKD trial was continuing unchanged. The press release failed to mention the numerous issues specific to having relied upon a single pivotal Phase 3 trial and otherwise hid the severity of the issues that it did share.

180. On October 29, 2020, Tricida announced that during an End-of-Review Type A conference held October 20, 2020, with the FDA's Division of Cardiology and Nephrology—which had issued the CRL on August 21, 2020, denying Tricida's veverimer NDA—the FDA told Tricida that it was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would therefore "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program." But because Tricida could not provide this interim information from the VALOR-CKD trial "without compromising the integrity of the ongoing trial," additional trials would be required to gather this information. In other words, the FDA rejected the veverimer NDA because Tricida had failed to demonstrate that the single phase 3 trial's surrogate endpoint could reasonably predict clinical efficacy. Tricida suggested that this was the first time the FDA had called into question Tricida's use of serum bicarbonate to measure efficacy, noting that the Company's discussions with the FDA over nearly four years "focused on development of veverimer based solely on the use of serum bicarbonate as the surrogate endpoint to enable accelerated approval, with CKD progression data to be provided only at the completion of the VALOR-CKD trial." [redacted]

[redacted]

[redacted] The same press release disclosed that Tricida was "significantly reducing its headcount from 152 to 59 people and will discuss its commitments with vendors and contract service providers to potentially provide additional financial flexibility."

181. In response to this news, Tricida's stock price fell $3.90 per share, to close at $4.37 per share on October 29, 2020.

182. The October 29, 2020, press release revealed for the first time that Tricida would have to provide clinical evidence of CKD progression (instead of just chemical evidence of serum bicarbonate levels), and that that evidence would have to come from the VALOR-CKD trial or some other yet-to-be designed trial. However, acquiring that evidence from the VALOR-CKD trial would eliminate its ability to function as a confirmatory postmarketing trial for purposes of the accelerated approval process. The press release still said nothing about either the numerous issues specific to having relied upon a single pivotal Phase 3 trial [redacted] Although the announced reduction in headcount suggested that near-term commercialization of veverimer was not likely, the press release emphasized that there was still a path forward because the company "plans to wait for formal meeting minutes from the FDA related to the End-of-Review Type A meeting prior to determining how to proceed with obtaining regulatory approval for veverimer."

183. On December 8, 2020, sixteen minutes before trading closed for the day, Tricida announced that it had revised the protocol for the VALOR-CKD trial to replace an "adaptive design" and "interim analysis for sample size adjustment" with "a group sequential design" and "an unblinded interim analysis for early stopping for efficacy." Tricida had scrapped plans providing any semblance of near-term approval prospects for veverimer. The press release also provided an update on the regulatory status of the veverimer NDA:

> A Formal Dispute Resolution Request (FDRR) has been submitted to the FDA to seek clarity on the path forward for resubmitting our New Drug Application (NDA) through the Accelerated Approval Program. The FDRR requests that the Office of New Drugs (OND) find that the magnitude of serum bicarbonate change seen in the TRCA-301 and TRCA-301E trials is reasonably likely to predict clinical benefit in the treatment of metabolic acidosis associated with CKD and that it can therefore serve as the basis for accelerated approval. If accepted for consideration, a decision on the FDRR

> is expected in the first quarter of 2021. The timing and next steps for a resubmission of the NDA for veverimer will be dependent upon the OND's decision.
>
> "We believe that we are studying the right patient population and the right CKD progression endpoint in VALOR-CKD. Hence, we believe that an adaptive design is no longer necessary and have locked in the sample size at 1,600 subjects and built in two opportunities for stopping early for efficacy over the next 18 to 24 months, in the event that the effect of veverimer on slowing CKD progression is greater than currently modeled," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "And while we are disappointed that we could not come to a resolution with the Division of Cardiology and Nephrology on the resubmission of our NDA during our Type A meeting, we believe that the focused, single issue FDRR currently represents the best approach to bring veverimer to patients through accelerated approval."

184. The press release, like earlier press releases, focused on one issue with the NDA: the surrogate endpoint's ability to predict clinical benefit. This time, the press release presented a new way—the FDRR—for the FDA to approve the NDA. Importantly, the press release still said nothing about either the numerous issues specific to having relied upon a single pivotal Phase 3 trial. Tricida's stock price fell from its closing price of $8.12 per share on December 8, 2020, to close at $6.68 per share on December 9, 2020, an almost 18% decline.

185. Twenty-five minutes before markets closed on February 25, 2021, Tricida announced in a press release that the Company had "received an Appeal Denied Letter (ADL), from the Office of New Drugs (OND) of the FDA in response to its Formal Dispute Resolution Request (FDRR) submitted in December 2020." According to Tricida, the FDA's ADL said the "extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression," and "the confirmatory trial, VALOR-CKD, is underpowered …." The press release also publicly revealed for the first time the FDA's "concerns that are particularly relevant in an NDA supported by a single registration trial": the trial results were "strongly influenced by a single site," and "the majority of sites for the TRCA-301/TRCA-301E trial" were in Eastern Europe, "where differences in patient management … might affect the treatment response to veverimer," rendering questionable "the applicability to a U.S. patient population." This press release finally revealed the numerous

deficiencies plaguing the veverimer NDA, all of which the Company had known about long before it even submitted the NDA.

186. On this news, Tricida's stock price fell from $7.36 per share at close on February 25, 2021 to $5.11 per share at close on February 26, 2021.

ADDITIONAL ALLEGATIONS OF SCIENTER

187. Throughout the class period, Defendant Klaerner sold nearly $10 million in shares of Tricida stock. When he made these sales of Tricida stock, he was privy to the complete—and nonpublic—collection of risks related to the veverimer NDA's likelihood for FDA approval. He knew that his and Tricida's failure to disclose the full risk profile for veverimer's FDA review had inflated the value of Tricida stock. He has only made a single purchase of Tricida stock (ever), which occurred on July 2, 2018. He purchased 15,790 shares at a price of $19.00 apiece. He made 34 sales of Tricida stock between December 26, 2018 and February 8, 2021, totaling $9,758,875. His sales were particularly aggressive from March 28, 2019—days before the secondary public offering—and December 18, 2019—while the hype of the recently-filed veverimer NDA remained fresh—during which period Tricida's stock consistently traded at prices between $30 and $43.50 per share. His trades during the class period were as follows:

Date	Transaction	Share Price	Shares Traded	Sum
02/08/21	Sell	$7.26	8,000	$58,080
01/13/21	Sell	$7.39	16,690	$123,292
01/12/21	Sell	$7.65	9,821	$75,131
01/11/21	Sell	$7.49	21,489	$160,953
07/15/20	Sell	$26.33	4,000	$105,320
07/01/20	Sell	$27.15	4,000	$108,600
06/15/20	Sell	$25.97	4,000	$103,869
06/01/20	Sell	$26.23	4,000	$104,920
05/15/20	Sell	$31.55	4,000	$126,220
05/01/20	Sell	$27.98	4,000	$111,906
04/15/20	Sell	$27.47	4,000	$109,891
04/06/20	Sell	$24.22	4,000	$96,880
03/16/20	Sell	$23.91	4,000	$95,640
03/02/20	Sell	$31.53	4,000	$126,120
02/18/20	Sell	$36.10	4,000	$144,400
02/03/20	Sell	$36.33	4,000	$145,330

01/15/20	Sell	$35.26	4,000	$141,040
01/02/20	Sell	$37.15	4,000	$148,607
12/18/19	Sell	$38.91	31,750	$1,235,457
12/11/19	Sell	$43.50	7,572	$329,346
12/10/19	Sell	$43.28	3,948	$170,869
12/01/19	Sell	$39.65	8,000	$317,160
11/01/19	Sell	$38.54	49,000	$1,888,556
10/28/19	Sell	$37.26	4,000	$149,035
10/01/19	Sell	$31.07	11,223	$348,663
09/30/19	Sell	$30.69	10,255	$314,734
08/28/19	Sell	$33.71	4,000	$134,840
07/29/19	Sell	$31.17	4,000	$124,680
07/06/19	Sell	$35.55	5,826	$207,097
07/03/19	Sell	$37.08	6,874	$254,854
03/28/19	Sell	$32.96	57,822	$1,905,974
03/04/19	Sell	$23.76	853	$20,267
03/01/19	Sell	$23.94	7,147	$171,064
12/26/18	Sell	$25.02	4,000	$100,080
07/02/18	Buy	$19.00	15,790	$300,010

Most of these trades occurred as part of a 10b5-1 plan, but this 10b5-1 plan was itself first implemented amidst Klaerner and Tricida's ongoing securities fraud (which began as of the IPO). Indeed, Tricida made materially false statements about the TRCA-301 trial before shares of the Company were even available to the investing public. Klaerner traded on the nonpublic knowledge of the inflated value of Tricida's stock throughout the class period.

188. Tricida itself engaged in insider trades through the initial public offering on June 28, 2018, and again in the secondary offering on April 3-8, 2019. Tricida needed funds to operate and continue its postmarketing trials of veverimer so it sold common stock to the investing public in its IPO. Thereafter, it was in need of additional monies to fund its operations past early 2021, when the Company would be in the initial stages of commercializing veverimer if the NDA were approved by the PDUFA date in August 2020. Tricida had $243.4 million in cash, cash equivalents, and investments at the end of 2018. At the time of the secondary offering, however, Tricida already knew of the significant risks in obtaining FDA approval for veverimer and failed to reveal these material facts to investors. Indeed, Tricida knew that most of the TRCA-301/301E trials had been conducted in Eastern Europe and that one trial site in particular had a disproportionate effect on

the results, both of which severely undercut the credibility of the study results [redacted] Tricida sold 6.44 million shares of common stock, at $36 per share, for over $231 million by the time the secondary stock offering completed on April 8, 2019.

189. Tricida had only one drug candidate: veverimer. Accordingly, the day-to-day operations at the Company leading up and throughout the Class Period focused solely on shepherding veverimer through clinical trials and FDA approval to commercialization; the Company's entire future hung on the success of bringing veverimer to market. And Tricida was Klaerner's project through and through. He "started it in 2013 in his living room" shortly after "finishing up the Relypsa experience" and he "was looking for an opportunity to create something that is truly disease-modifying." Klaerner, who has a Ph.D. in polymer and organic chemistry and was an in-house scientist before founding several companies, is "very passionate about polymer chemistry," and demonstrates himself to be intimately familiar with the design and functionality of veverimer. Thus, Klaerner, as CEO was involved in and aware of even more than just the core operations at Tricida.

190. He was focused on the details and, given the small size and narrow focus of the Company, participated in meetings with lower-level employees working toward accomplishing a single component of the data needed to support an NDA. Klaerner attended meetings with and inspections by the FDA, including the May 6. 2015 meeting, the November 30, 2016 meeting, the February 9, 2017 meeting, the July 26, 2017 meeting, the March 6, 2018 meeting, the June 3, 2019 meeting, the January 27, 2020 meeting, and the May 1, 2020 meeting. Additionally, the Establishment Inspection Report for the inspection of Tricida's South San Francisco facility from December 9-17, 2019, reports that the FDA inspector met with Klaerner before the facility inspection and afterwards to debrief the results. Additionally, Confidential Witness 2 ("CW2")—who served in the role of Executive Director of Operations from September 2019 through October 2020 and was responsible for overseeing the commercialization of veverimer after (hopeful) FDA approval—stated that at numerous meetings, Klaerner told the assembled company executives that he was waiting to hear from the FDA about setting up a meeting with the Agency.

LOSS CAUSATION / ECONOMIC LOSS

191. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially inflated the price of Tricida stock and operated as a fraud or deceit on Class Period purchasers of Tricida stock by misrepresenting and omitting material information about the design and execution of the TRCA-301/TRCA-301E trials. When Defendants' prior misrepresentations and omissions were disclosed to the market, beginning on July 15, 2020, Tricida's stock price fell as the prior artificial inflation came out of the price. The full inflation did not come out of the stock price until February 25, 2021. As a result of their purchases of Tricida stock during the Class Period, Lead Plaintiff and other members of the Class suffered economic loss, i.e., damages, under the federal securities laws.

192. Defendants' misleading statements and omissions of material facts, identified herein at ¶¶94-173, had the intended effect and caused Tricida stock to trade at artificially inflated prices during the Class Period.

193. As a direct result of the disclosures that began after the markets closed on July 15, 2020, as detailed in ¶¶174-76, Tricida's stock price suffered a significant decline. On July 16, 2020, the price of Tricida stock, which traded on NASDAQ, fell from the prior days close of $26.20 to a low of $15.64, a drop of 40.31% after the market learned that Tricida's veverimer NDA suffered from review issues that were significant enough to preclude discussions of labeling and postmarketing requirements/commitments.

194. In addition, the disclosure made before the markets opened on August 24, 2020, as detailed in ¶¶177-79, directly caused Tricida's stock price to fall. On August 24, 2020, Tricida's stock price fell from a close of $13.24 per share on August 21, 2020, to close at $10.11 per share—a drop of 23.64%—after learning that Tricida had received a CRL from the FDA in response to the veverimer NDA.

195. The disclosure before the markets opened on October 29, 2020, as detailed in ¶¶180-82, also had a direct impact on Tricida's stock price. The price of Tricida's stock plummeted from $8.27 at close on October 28, 2020, to $4.37 at close on October 29, 2020—a drop of 47.16%—in direct response to additional disclosures regarding review issues with the veverimer

NDA and its likelihood for near-term approval. Specifically, Tricida revealed that the FDA told Tricida that it was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would therefore "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program."

196. Tricida's stock price again suffered as a direct result of the disclosures made sixteen minutes before the markets closed on December 8, 2020, as detailed in ¶¶183-84, which revealed (1) that Tricida had failed to come to an agreement with the FDA on the resubmission of the veverimer NDA during the Type A meeting, (2) that the Company had filed a FDRR in an attempt to convince the FDA that the TRCA-301 trial results are reasonably likely to predict clinical benefit, and (3) that the Company had scrapped the protocol for the VALOR-CKD trial. In direct response, Tricida's stock price fell 17.73% from $8.12 per share at close on December 8, 2020 to close at $6.68 per share on December 9, 2020.

197. The final disclosures on February 25, 2021, as detailed in ¶¶185-86, directly caused Tricida's stock price to fall from $7.36 per share at close on February 25, 2021 to close at $5.11 on February 26, 2021—a drop of 30.57%. Twenty-five minutes before the markets closed on February 25, 2021, Tricida disclosed that it had received an ADL from the FDA, which determined (1) the "extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression," (2) "the confirmatory trial, VALOR-CKD, is underpowered," (3) the trial results were "strongly influenced by a single site," and (4) "the majority of sites for the TRCA-301/TRCA-301E trial" were in Eastern Europe, "where differences in patient management … might affect the treatment response to veverimer," rendering questionable "the applicability to a U.S. patient population."

198. The declines in Tricida's stock price on July 16, 2020, August 24, 2020, October 29, 2020, December 8, 2020, and February 25, 2021, were a direct result of the nature and extent of Defendants' prior misstatements and omissions being revealed to investors and the market.

199. The timing and magnitude of Tricida's stock price decline negates any inference that the losses suffered by Lead Plaintiffs and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific factors unrelated to

Defendants' fraudulent conduct. On July 16, 2020, the Nasdaq was down only -0.7%, with the Nasdaq U.S. Smart Pharmaceuticals Index down even less, at -0.4%. On August 24, 2020, the Nasdaq increased 0.01%, and the Nasdaq Smart Pharma was down only -0.3%. On October 29, 2020, the Nasdaq increased 1.6% and the Nasdaq Smart Pharma increased 0.4%. On December 8, 2020, the Nasdaq decreased 0.02% and the Nasdaq Smart Pharma increased 1.46%. On February 25, 2021, the Nasdaq decreased 0.04%, while the Nasdaq Smart Pharma decreased -1.5%.

200. The losses suffered by Lead Plaintiff and other members of the Class were a direct result of Defendants' fraudulent scheme to inflate Tricida's stock price and the subsequent, significant declines in the value of that stock when Defendants' prior misrepresentations and omissions were revealed.

CLASS ACTION ALLEGATIONS

201. Lead Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), on behalf of a class consisting of all purchasers of the common stock of Tricida during the Class Period (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

202. The members of the Class are so numerous that joinder of them is impracticable. Throughout the Class Period, Tricida traded on the NASDAQ exchange. While the exact number of class members is not presently known to Lead Plaintiff, and can only be ascertained through discovery, Lead Plaintiff believes there are thousands of members in the proposed Class. Record owners and other members of the Class can be ascertained through records maintained by Tricida and/or its transfer agent. Those record holders could be notified of the pendency of this action by mail.

203. Lead Plaintiff's claims are typical of the claims of the members of the Class, as all are similarly affected by Defendants' wrongful conduct in violation of federal law.

204. Lead Plaintiff will fairly and adequately protect the interests of the members of the class and has retained competent and experienced securities litigation counsel.

205. Common questions of law and fact exist as to all members of the Class and will predominate over any questions solely affecting individual members of the Class. Among the common questions of law and fact common to the Class:

a. Whether the Exchange Act was violated by Defendants as alleged herein;

b. Whether statements made by Defendants misrepresented and omitted material facts about Tricida's business, operations, and management; and

c. To what extent the members of the Class have suffered damages, and the proper measure of those damages.

206. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, given that joinder of all members is impracticable. As the damages suffered by each individual Class member may be relatively small, the burden and expense of litigating individual cases would make it all but impossible for many members of the Class to redress wrongs done to them. There will not be any difficulty in managing this action as a class action.

FRAUD ON THE MARKET

207. Lead Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine. Among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. These omissions and material misrepresentations were material;

c. Tricida common stock traded in an efficient market throughout the Class Period;

d. The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Tricida common stock; and

e. Lead Plaintiff and other members of the Class purchased Tricida common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

208. At all relevant times, the market for Tricida common stock was efficient, as:

a. Tricida filed periodic public reports with the SEC as a regulated issuer; and

b. Tricida regularly communicated with public investors via established communications mechanisms, including through the regular dissemination of press releases on major news wire services, communications through the financial press, securities analysts, the internet, and other similar reporting services.

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

209. Lead Plaintiff incorporates ¶¶1-208 by reference.

210. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and concealed material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

211. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

212. Employed devices, schemes, and artifices to defraud;

213. Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

214. Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Tricida securities during the Class Period.

215. In addition to the duties of full disclosure imposed on Defendants as a result of their affirmative false and misleading statements to the public, the Exchange Act Defendants had a duty to promptly disseminate truthful information with respect to Tricida's operations and performance that would be material to investors in compliance with the integrated disclosure provisions of the SEC, including with respect to the Company's revenue and earnings trends, so that the market prices of the Company's securities would be based on truthful, complete, and accurate information. SEC Regulations S-X (17 C.F.R. §210.01, et seq.) and S-K (17 C.F.R. §229.10, et seq.).

216. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the Class have suffered damages in connection with their respective purchases of Tricida common stock during the Class Period, because, in reliance on the integrity of the market, they paid artificially inflated prices for Tricida securities and experienced losses when the artificial inflation was released from Tricida securities as a result of the revelations and prices decline detailed herein. Plaintiffs and the Class would not have purchased Tricida securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

217. By virtue of the foregoing, Tricida and Klaerner have each violated §10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

COUNT II

For Violations of Section 20(a) of the Exchange Act Against Defendant Klaerner

218. Lead Plaintiff incorporates ¶¶1-208 by reference.

219. During his tenure as officer and director of Tricida, Klaerner and Tricida were controlling persons of the Company within the meaning of §20(a) of the Exchange Act. By reason of their positions of control and authority as officer and director of Tricida, Klaerner and Tricida had the power and authority to cause Tricida to engage in the conduct complained of herein. These defendants were able to, and did, control, directly and indirectly, the decision-making of Tricida, including the content and dissemination of Tricida's public statements and filings described herein, thereby causing the dissemination of the materially false and misleading statements and omissions as alleged herein. Tricida exercised control over and directed the actions of its senior managers, directors and agents, including Defendant Klaerner. Tricida controlled Defendant Klaerner and all of its employees and subsidiaries.

220. In his capacity as chief executive officer and director of Tricida, and as more fully described herein, Defendant Klaerner participated in the misstatements and omissions set forth above. Indeed, Klaerner had direct and supervisory involvement in the day-to-day operations of the Company and had access to non-public information regarding Tricida's deceptive and risky business practices. Defendants had the ability to influence and direct and did so influence and

direct the activities of Defendants in their violations of §10(b) of the Exchange Act and Rule 10b-5 as detailed in ¶¶211-19.

221. As a result, Defendants were control persons within the meaning of §20(a) of the Exchange Act.

222. As set forth above, Tricida violated §10(b) of the Exchange Act. By virtue of its position, and as a result of its aforementioned conduct and culpable participation, Tricida is liable pursuant to §20(a) of the Exchange Act, jointly and severally with, and to the same extent as Defendant Klaerner is liable to Plaintiffs and the other members of the Class. Tricida exercised control over Klaerner and all of its employees and subsidiaries and, as a result of its aforementioned conduct and culpable participation, is liable pursuant to §20(a) of the Exchange Act, jointly and severally with, and to the same extent as the Klaerner is liable to Plaintiffs and the other members of the Class.

223. This claim is brought within the applicable statute of limitations.

224. By reason of the foregoing, Defendants violated §20(a) of the Exchange Act, 15 U.S.C. §78(a).

PRAYER FOR RELIEF

225. WHEREFORE, Lead Plaintiff prays for relief and judgment as follows:

a. Declaring the action to be a proper class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein;

b. Awarding all damages and other remedies available under the Securities Exchange Act in favor of Lead Plaintiff and all members of the Class against Defendants in an amount to be proven at trial, including interest thereon;

c. Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

d. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

226. Lead Plaintiff demands a trial by jury.

December 15, 2022

Respectfully submitted,

/s/ Jacob A. Walker

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EXHIBIT C

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	)	Chapter 11
	)	Case No. 23-10024 (JTD)
Tricida, Inc., [1]	)	
Debtor.	)	**Related Docket No. ___**

ORDER SUBORDINATING CLAIM NO. 144 FILED BY JEFFREY FIORE, AS SECURITIES LEAD PLAINTIFF FOR A PROPOSED CLASS OF PLAINTIFFS, AND CLAIM NO. 146 FILED JEFFREY FIORE INDIVIDUALLY PURSUANT TO 11 U.S.C. § 510(B)

Upon consideration of the *Motion of the Liquidating Trustee to Subordinate Claim No. 144 filed by Jeffrey Fiore, as Securities Lead Plaintiff for a Proposed Class of Plaintiffs, and Claim No. 146 filed by Jeffrey Fiore Individually Pursuant to 11 U.S.C § 510(b)* (the "Motion"); and with due and sufficient notice of the Motion having been given under the particular circumstances; and it appearing that no other or further notice need be provided; and this Court having jurisdiction over this matter pursuant to 28 U.S.C. §§ 157 and 1334 and the *Amended Standing Order of Reference from the United States District Court for the District of Delaware,* dated February 29, 2012; and finding that the Court has authority to enter a final order in this matter consistent with Article III of the United States Constitution, and this matter being a core proceeding pursuant to 28 U.S.C. §§ 1408 and 1409, and it appearing that the relief requested by the Motion is in the best interests of the Liquidating Trust, [2] all creditors, and other parties in interest and after due deliberation thereon; and good and adequate cause appearing therefor,

IT IS HEREBY ORDERED THAT:

1. The Motion is granted as set forth herein.

[1] The Debtor in this chapter 11 case, together with the last four digits of the Debtor's federal tax identification number, is Tricida, Inc. (2526).

[2] Capitalized terms used but not otherwise defined herein shall have the meaning ascribed to such terms in the Motion.

2. Claim No. 144 filed by Jeffrey Fiore, as Securities Lead Plaintiff for a Proposed Class of Plaintiffs, and Claim No. 146 filed by Jeffrey Fiore individually shall be, and hereby are, subordinated to the same priority as Tricida's common stock pursuant to 11 U.S.C. § 510(b).

3. This Court shall retain jurisdiction to resolve any dispute relating to the interpretation or enforcement of this Order.