UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PLAINTIFF, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. TRICIDA, INC., GERRIT KLAERNER, and GEOFFREY M. PARKER, Defendants.	Case No. CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

Plaintiff, individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Tricida, Inc. ("Tricida" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Tricida securities between September 4, 2019 and October 28, 2020, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Tricida was founded in 2013 and is headquartered in South San Francisco, California. Tricida is a pharmaceutical company that focuses on the development and commercialization of its drug candidate, veverimer (TRC101), a non-absorbed, orally-administered polymer designed as a potential treatment for metabolic acidosis in patients with chronic kidney disease ("CKD"). Tricida has completed a Phase 3, double-blind, placebo-controlled trial of veverimer in patients with CKD and metabolic acidosis.

3. On September 4, 2019, Tricida announced that it had submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") under the Accelerated Approval Program for approval of veverimer for the treatment of metabolic acidosis in patients with CKD.

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Tricida's NDA for veverimer was materially deficient; (ii) accordingly, it was foreseeably likely that the FDA would not accept the NDA for veverimer; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On July 15, 2020, Tricida issued a press release announcing that, on July 14, 2020, the Company received a notification from the FDA, stating that as part of the FDA's ongoing review of the Company's NDA for veverimer, "the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." Tricida stated that "[t]he notification does not specify the deficiencies identified by the FDA."

6. On this news, Tricida's stock price fell $10.56 per share, or 40.31%, to close at $15.64 per share on July 16, 2020.

7. Then, on October 29, 2020, Tricida announced an update on its End-of-Review Type A meeting with the FDA regarding the veverimer NDA, advising investors that the Company "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." Concurrently, Tricida disclosed that it "is 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."

8. On this news, Tricida's stock price fell $3.90 per share, or 47.16%, to close at $4.37 per share on October 29, 2020.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

10. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

12. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Tricida is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.

13. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

14. Plaintiff, as set forth in the attached Certification, acquired Tricida securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

15. 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."

16. Defendant Gerrit Klaerner, Ph.D. ("Klaerner") has served as Tricida's Chief Executive Officer and President at all relevant times.

17. Defendant Geoffrey M. Parker ("Parker") has served as Tricida's Chief Financial Officer and Senior Vice President at all relevant times.

18. Defendants Klaerner and Parker are sometimes referred to herein as the "Individual Defendants."

19. The Individual Defendants possessed the power and authority to control the contents of Tricida's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Tricida's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Tricida, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

20. Tricida and the Individual Defendants are sometimes collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

21. Tricida was founded in 2013 and is headquartered in South San Francisco, California. Tricida is a pharmaceutical company that focuses on the development and commercialization of its drug candidate, veverimer (TRC101), a non-absorbed, orally-administered polymer designed as a potential treatment for metabolic acidosis in patients with CKD. Tricida has completed a Phase 3, double-blind, placebo-controlled trial of veverimer in patients with CKD and metabolic acidosis.

Materially False and Misleading Statements Issued During the Class Period

22. The Class Period begins on September 4, 2019, when, during pre-market hours, Tricida issued a press release announcing that it had submitted an NDA to the FDA under the Accelerated Approval Program for approval of veverimer for the treatment of metabolic acidosis in patients with CKD. That press release also stated, in relevant part:

> The NDA submission is supported by data from Tricida's successful Phase 3 clinical trials that were recently published in back-to-back publications in The Lancet (March 2019 and June 2019).
>
> "This submission under the FDA's Accelerated Approval Program could provide the first and only FDA-approved therapy to this underserved population of patients with chronic kidney disease and metabolic acidosis," said Gerrit Klaerner, PhD, Tricida's Founder, Chief Executive Officer and President. "We are grateful for the patients who participated in our clinical trials, our clinical investigators and the entire Tricida team who have made this journey possible. It is notable that the process from generating the idea to treat metabolic acidosis to the in-house discovery, development and NDA submission of veverimer was achieved in less than 6 years. We now look forward to the potential approval and launch of veverimer next year."

23. On November 14, 2019, Tricida issued a press release announcing that the FDA had accepted the Company's NDA for veverimer. That press release also stated, in relevant part:

> In its correspondence, [the] FDA . . . stated that no filing review issues [with the NDA for veverimer] were identified. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 22, 2020 and indicated that it is currently planning to hold a Cardiovascular and Renal Drugs Advisory Committee meeting to discuss the application.
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> The NDA submission is supported by data from Tricida's successful Phase 3 clinical trials that were recently published in back-to-back publications in *The Lancet* (March 2019 and June 2019).
>
> "We are pleased that our application for veverimer was accepted for review under the Accelerated Approval Program and look forward to engaging with experts at an advisory committee meeting," said Gerrit Klaerner, Ph.D., Tricida's chief executive officer and president. "With a potential approval in August 2020, veverimer would be the first and only FDA-approved therapy for the chronic treatment of metabolic acidosis in patients with CKD. Our commercial team is targeting a successful launch with a full quarter of revenue in the fourth quarter of 2020."

24. That same day, Tricida issued a press release announcing the Company's third quarter 2019 financial results. The press release listed as one of the Company's highlights:

> Announced separately today that the U.S. Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) for veverimer under the Accelerated Approval Program. In its correspondence, FDA also stated that no filing review issues were identified. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 22, 2020 and indicated that it is currently planning to hold a Cardiovascular and Renal Drugs Advisory Committee (CRDAC) meeting to discuss the application.

In addition, the press release quoted Defendant Klaerner, stating, in relevant part:

> "We are pleased that our application for veverimer was accepted for review under the Accelerated Approval Program and look forward to engaging with experts at an advisory committee meeting," said Gerrit Klaerner, Ph.D., Tricida's chief executive officer and president. "With a potential approval in August 2020, veverimer would be the first and only FDA-approved therapy for the chronic treatment of metabolic acidosis in patients with CKD. Our commercial team is targeting a successful launch with a full quarter of revenue in the fourth quarter of 2020."

25. Also that same day, Tricida filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating performance for the quarter ended September 30, 2019 (the "Q3 2019 10-Q"). In providing an overview of the Company, the Q3 2019 10-Q stated, in relevant part:

> In August 2019, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, seeking approval to market veverimer. We subsequently received the FDA's filing communication letter, or Day 74 Letter, which stated that our NDA had been accepted for review by the FDA under the Accelerated Approval Program and that a user fee goal date of August 22, 2020 had been set under the Prescription Drug User Fee Act. The Day 74 Letter also stated the FDA is currently planning to hold an advisory committee meeting to discuss the NDA, which we believe would likely occur in the first half of 2020.
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> Veverimer is an in-house discovered, new chemical entity, that we believe may effectively treat metabolic acidosis and slow the progression of kidney disease in CKD patients with metabolic acidosis.
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> We estimate that metabolic acidosis affects approximately 3 million CKD patients in the United States, and we believe that slowing the progression of CKD in patients with metabolic acidosis represents a significant medical need and market opportunity. If approved, we plan to commercialize veverimer in the United States initially using a nephrologist-focused sales force. To address markets outside of the United States, we plan to seek one or more partners with international sales expertise who can sell veverimer in target markets. We have an intellectual property estate that we believe will provide patent protection for veverimer until at least 2034 in the United States, the European Union, Japan, China, India and certain other markets. Tricida is led by a seasoned management team that includes a founder of Ilypsa, Inc. and Relypsa, Inc. Our management team has extensive experience in the development and commercialization of therapeutics, with deep expertise in developing polymers for the treatment of kidney-related diseases.

26. Appended to the Q3 2019 10-Q as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, attesting that, "[t]he information contained in [the Q3 2019 10-Q] fairly presents, in all material aspects, the financial condition and results of operations of the Company."

27. Finally, also that same day, Tricia hosted an earnings call with investors and analysts to discuss the Company's third quarter 2019 results (the "Q3 2019 Earnings Call"). During the scripted portion of the Q3 2019 Earnings Call, Defendant Klaerner stated, in relevant part:

> We are pleased to report that our veverimer NDA has been accepted for a review by the FDA under the Accelerated Approval Program with no filing review issues identified. The application is under review by the division of cardiovascular and

> renal products as a standard review designation and the PDUFA goal date of August 22, 2020. As a reminder, this filing acceptance under the Accelerated Approval Program underscores the fact that metabolic acidosis is a serious condition and as the veverimer, if approved, would address an unmet medical need.
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> The FDA has also indicated that they are currently – that they currently plan to hold an advisory committee meeting or AdCom to discuss the application. We anticipate the AdCom would likely occur in the first half of 2020 and we will know the topics of discussion closer to the meeting date.

In addition, when asked a question regarding why the FDA would want an Advisory Committee meeting, Defendant Klaerner responded:

> I've learned over the years not to speculate and I think we're obviously very excited to actually present our data. I think both from the perspective of standard review and the outcome, when you look at our program we are among the first to really utilize the accelerated approval path with a renal indication and when we had our pre-NDA meeting, I think we shared all the data with them that we had available, including the data beyond the surrogate. So again, I'm not speculating about any potential topics for the AdCom, but this is exciting. I mean I think not many people have had pursued a major disease-modifying renal indication under Subpart H.

28. On February 27, 2020, Tricida issued a press release announcing the Company's fourth quarter and full year 2019 financial results. The press release included as one of the Company's highlights:

> The U.S. Food and Drug Administration (FDA) accepted for review, through the Accelerated Approval Program, Tricida's New Drug Application (NDA) for veverimer and has assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 22, 2020. The FDA has indicated that it is currently planning to hold a Cardiovascular and Renal Drugs Advisory Committee (CRDAC) meeting to discuss the application.

In addition, the press release quoted Defendant Klaerner, stating, in relevant part:

> "We are rapidly transforming Tricida into a commercial organization that is preparing to launch veverimer, if approved, as the first and only FDA-approved therapy to treat metabolic acidosis and potentially slow CKD progression," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We believe there is an urgent need to effectively and safely treat this serious condition. We are working with the FDA to obtain initial approval through the Accelerated Approval Program to market veverimer in the United States."

29. That same day, Tricida hosted an earnings call with investors analysts to discuss the Company's fourth quarter 2019 results (the "Q4 2019 Earnings Call"). During the scripted portion of the Q4 2019 Earnings Call, Defendant Klaerner stated, in relevant part:

> . . . the key goal for Tricida in 2020[] [is] the planning and execution of the successful launch of the veverimer. Our PDUFA goal date is just six months away and we are engaged in multiple activities to ensure the successful launch of veverimer in the fourth quarter of this year and sales growth in 2021 and beyond.
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> [W]ith respect to our NDA, we will not be providing updates on our discussions or interactions with the FDA during the review process other than to say that the routine matters around our submission are on the way and we'll continue to work with the FDA to enable them to complete the review in a timely manner. The FDA is planning to hold an advisory committee meeting or AdCom to accept the application.
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> We're anticipating that the outcome would likely occur in the second quarter of 2020 and we'll know the topic of discussion closer to the meeting date. As we said previously, given that we are pursuing a potential disease-modifying indication in CKD, utilizing the accelerated approval program we welcome this opportunity and we will be prepared to present the underlying rationale and the considerable body of evidence supporting the treatment of metabolic acidosis closes the progression of kidney disease.

In addition, when asked a question regarding Tricida's plans for European filing of veverimer, Defendant Klaerner responded, in relevant part, "[o]ur plans continue to be that we will have substantive engagement with European regulatory authorities starting just after our expected approval in the U.S. So that would be post the August 22nd, PDUFA date."

30. On March 2, 2020, Tricida filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2019 (the "2019 10-K"). The 2019 10-K stated, in relevant part:

> Our [NDA] for veverimer as a chronic treatment for metabolic acidosis in patients with CKD, is currently under review by the U.S. Food and Drug Administration, or FDA, through the Accelerated Approval Program. [. . . .]
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> Results from our positive Phase 3, 12-week efficacy trial, TRCA-301, and a follow-on 40-week extension trial, TRCA-301E, formed the primary clinical basis of our

NDA submission. The Lancet published the results of the TRCA-301 trial in March 2019 and the results of the TRCA-301E trial in June 2019.

* * *

We believe the data from our TRCA-301 and TRCA-301E trials provide strong evidence that veverimer can effectively raise serum bicarbonate levels in patients with metabolic acidosis and CKD, and potentially slow progression of CKD as well as provide a clinically meaningful difference in physical function related quality of life and daily physical functioning.

31. Further, in discussing the Company's strategies, the 2019 10-K stated, in relevant part:

Our strategy is to develop and commercialize veverimer as the first and only FDA-approved therapy for the treatment of metabolic acidosis and slowing of kidney disease progression in patients with metabolic acidosis associated with CKD for the large population of patients with metabolic acidosis and CKD. Key elements of our strategy are to:

- Obtain FDA approval of veverimer. The veverimer NDA is currently under review through the FDA's Accelerated Approval Program. The FDA has assigned a PDUFA goal date of August 22, 2020 for the potential approval to market veverimer in the United States.

32. Finally, in discussing the Company's development program for veverimer, the 2019 10-K stated, in relevant part:

Our NDA for veverimer is under review by the FDA through the Accelerated Approval Program for potential approval as the first and only FDA-approved therapy for the treatment of metabolic acidosis and slowing of kidney disease progression in patients with metabolic acidosis associated with CKD. It has been assigned a PDUFA goal date of August 22, 2020 for the potential approval to market veverimer in the United States. The FDA has indicated that it is currently planning to hold a CRDAC meeting to discuss the NDA. The key clinical trials included in the NDA are our successful 135-subject, Phase 1/2 trial, TRCA-101, a successful 217-subject, pivotal Phase 3 clinical trial, TRCA-301 and a successful 196-subject, Phase 3 extension trial, TRCA-301E.

Both TRCA-101 and the pivotal study, TRCA-301, utilized change from baseline in serum bicarbonate as their primary endpoint. Eligible subjects who completed the 12-week treatment period in the pivotal TRCA-301 trial were invited to continue in our extension trial, TRCA-301E. The primary endpoint of the TRCA-301E trial was the assessment of the long-term safety profile of veverimer versus placebo. 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.
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> As part of the Accelerated Approval Program, we are currently conducting a confirmatory postmarketing trial, known as the VALOR-CKD trial, or TRCA-303, to evaluate the efficacy and safety of veverimer in delaying CKD progression in subjects with metabolic acidosis. We initiated the VALOR-CKD confirmatory postmarketing trial in the fourth quarter of 2018.

33. Appended to the 2019 10-K as an exhibit were signed certifications pursuant to SOX by the Individual Defendants, attesting that, "[t]he information contained in [the 2019 10-K] fairly presents, in all material aspects, the financial condition and results of operations of the Company."

34. On May 7, 2020, Tricida issued a press release announcing the Company's first quarter 2020 financial results. The press release included as the Company's "Upcoming Events and Projected Milestones," in relevant part, "Veverimer PDUFA goal date of August 22, 2020[,]" and "[c]ommercial launch of veverimer anticipated in the second half of 2020, which will include an extensive digital campaign to expand the reach of our promotional efforts for veverimer, if approved."

35. That same day, Tricida hosted an earnings call with investors and analysts to discuss the Company's first quarter 2020 results (the "Q1 2020 Earnings Call"). During the scripted portion of the Q1 2020 Earnings Call, Defendant Klaerner stated, in relevant part:

> 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 veverimer satisfies 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.
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> Under the initial approval, we have to ensure that U.S. 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.

36. In addition, when asked whether there may be a risk that the FDA wouldn't be comfortable approving a product on the merits of one study, Defendant Klaerner responded, in relevant part:

> . . . obviously we have an accelerated approval. You have to demonstrate a surrogate effect that is likely going to -- reasonably likely going to translate to clinical benefit, and then have the ability to design an outcome trial, which we've done and that outcome trial is ongoing well on its way, and that's very clear. And then on top of it obviously, while that outcome trial is going on for a few years, you also have to ensure that the patients who are getting it on and the initial approval in the U.S. patients are really getting clinical benefit. And those are the two components that -- and the two boxes we need to check and when you look at our back to back Lancet papers, when you look at the safety data, when you look at the efficacy data, both on the surrogate and beyond the surrogate in terms of the physical functioning, the quality-of-life and the objective chair test data, we are very confident that this is a very favorable risk benefit profile.
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> So we don't see -- our read on the overall situation has really not changed and I think we remain confident that the drug will be approved on August 22 and again I think that you're right, this is not oncology that has done a lot of Accelerated Approvals, so we don't have a lot of things to point to, where this has successfully worked. I think that's a fair statement.

37. On May 8, 2020, Tricida filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2020 (the "Q1 2020 10-Q"). The Q1 2020 10-Q stated, in relevant part:

> Our [NDA] for veverimer as a chronic treatment for metabolic acidosis, is currently under review by the [FDA] through the Accelerated Approval Program. Results from our positive Phase 3, 12-week efficacy trial, TRCA-301, and a follow-on 40-week extension trial, TRCA-301E, formed the primary basis of our NDA submission. 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). The TRCA-301E trial met its primary and all secondary endpoints. The Lancet published the results of the TRCA-301 trial in March 2019 and the results of the TRCA-301E trial in June 2019.
>
> The FDA has assigned a Prescription Drug User Fee Act, or PDUFA, goal date of August 22, 2020 for the potential approval to market veverimer in the United States. At this time, we do not believe the COVID-19 pandemic has affected our PDUFA goal date of August 22, 2020. We continue to work cooperatively with the FDA on review matters related to our NDA. In the filing communication letter received from the FDA, also referred to as the Day 74 Letter, the FDA indicated that it planned to hold a Cardiovascular and Renal Drugs Advisory Committee, or CRDAC, meeting

> 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 a CRDAC meeting to discuss veverimer, due, in part, to the logistical challenges posed by COVID-19. The lack of an advisory committee meeting should not be interpreted to indicate that there are no review issues being discussed with the FDA or that we will receive approval by the PDUFA goal date, if at all. In our late cycle meeting with the FDA, we had an opportunity to address the substantive review issues that have been raised to date. We presented our data and rationale as to why we think veverimer satisfies the requirements for initial approval under the Accelerated Approval Program, including 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 how U.S. patients who would be prescribed veverimer under the initial approval would get clinically significant benefit that outweighs the risk of treatment. While there can be no assurance that the FDA will agree, we remain confident that our submission meets the overall standard for approval under the Accelerated Approval Program.

38. Appended to the Q1 2020 10-Q as an exhibit were signed certifications pursuant to SOX by the Individual Defendants, attesting that, "[t]he information contained in [the Q1 2020 10-Q] fairly presents, in all material aspects, the financial condition and results of operations of the Company."

39. On August 5, 2020 Tricida hosted an earnings call with investors and analysts to discuss the Company's second quarter 2020 results (the "Q2 2020 Earnings Call"). During the scripted portion of the Q2 2020 Earnings Call, Defendant Klaerner stated, in relevant part:

> We were and continue to be surprised and disappointed by this notification from the FDA. We will be prepared to address the FDA's outstanding issues and plan to promptly request a Type A meeting, which are granted to typically resolve in a meeting with the FDA within 30 days of our request and submission of operating materials.
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> We've worked closely with the FDA during the veverimer program to gain approvals of the Accelerated Approval Program. Our goal is to continue this collaborative approach on any issues that the FDA raises in the future.
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> While we will work through any deficiencies cited by the FDA, it is important to note that we continue to believe that the fundamentals of veverimer itself based on our interaction with many expert nephrologists, we believe that veverimer continues to have an attractive compelling and positive benefit risk profile.

40. The statements referenced in ¶¶ 22-39 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Tricida's NDA for veverimer was materially deficient; (ii) accordingly, it was foreseeably likely that the FDA would not accept the NDA for veverimer; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

41. On July 15, 2020, Tricida issued a press release announcing that, on July 14, 2020, the Company received a notification from the FDA, stating that as part of the FDA's ongoing review of the Company's NDA for veverimer, "the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." Tricida stated that "[t]he notification does not specify the deficiencies identified by the FDA."

42. On this news, Tricida's stock price fell $10.56 per share, or 40.31%, to close at $15.64 per share on July 16, 2020.

The Truth Fully Emerges

43. Then, on October 29, 2020, Tricida announced an update on its End-of-Review Type A meeting with the FDA regarding the veverimer NDA, advising investors that the Company "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." Concurrently, Tricida disclosed that it "is 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."

44. On this news, Tricida's stock price fell $3.90 per share, or 47.16%, to close at $4.37 per share on October 29, 2020.

45. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

46. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Tricida securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, 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.

47. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Tricida securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Tricida or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

48. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

49. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

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

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Tricida;
- whether the Individual Defendants caused Tricida to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Tricida securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

51. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

52. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

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

- the omissions and misrepresentations were material;
- Tricida securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Tricida securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

53. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

54. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

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

55. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

56. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

57. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other

members of the Class; made various untrue statements of material facts and 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; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Tricida securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Tricida securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

58. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Tricida securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Tricida's finances and business prospects.

59. By virtue of their positions at Tricida, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant

knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

60. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Tricida, the Individual Defendants had knowledge of the details of Tricida's internal affairs.

61. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Tricida. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Tricida's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Tricida securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Tricida's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Tricida securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

62. During the Class Period, Tricida securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Tricida securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired

said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Tricida securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Tricida securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

63. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

64. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

65. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

66. During the Class Period, the Individual Defendants participated in the operation and management of Tricida, and conducted and participated, directly and indirectly, in the conduct of Tricida's business affairs. Because of their senior positions, they knew the adverse non-public information about Tricida's misstatement of income and expenses and false financial statements.

67. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Tricida's

financial condition and results of operations, and to correct promptly any public statements issued by Tricida which had become materially false or misleading.

68. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Tricida disseminated in the marketplace during the Class Period concerning Tricida's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Tricida to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Tricida within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Tricida securities.

69. Each of the Individual Defendants, therefore, acted as a controlling person of Tricida. By reason of their senior management positions and/or being directors of Tricida, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Tricida to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Tricida and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

70. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Tricida.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.