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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 25, 2020

TRICIDA, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**001-38558**	**46-3372526**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

7000 Shoreline Court
Suite 201
South San Francisco, CA 94080
(Address of principal executive offices) (Zip Code)
(415) 429-7800
(Registrant's telephone number, including area code)
N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common stock, par value $0.001 per share	TCDA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 2.05 Costs Associated with Exit or Disposal Activities.

On October 25, 2020, the Board of Directors of Tricida, Inc. (the "Company") approved and on October 28, 2020 management began implementing, a restructuring plan to reduce operating costs and better align its workforce with the needs of its business following the completion of the Company's End-of-Review Type A meeting with the U.S. Food and Drug Administration ("FDA") on October 20, 2020. The restructuring plan is expected to be completed in the fourth quarter of 2020.

Under the restructuring plan, the Company is reducing its workforce by 93 employees (approximately 60%). Impacted employees below the level of Vice President are eligible to receive severance benefits pursuant to the Company's 2020 Reduction in Force Severance Benefit Plan which includes a severance payment, a payment towards the cost of COBRA premiums and outplacement services. Impacted employees at the level of Vice President or above are eligible to receive severance benefits pursuant to the Company's Executive Severance Benefit Plan which includes a severance payment and a payment towards the cost of full COBRA premiums pursuant to the terms of their agreements. In each case, employee severance benefits are contingent upon an impacted employee's execution (and non-revocation) of a separation agreement, which includes a general release of claims against the Company. The Company expects that the workforce reduction will decrease its annual operating costs by approximately $24.9 million.

In connection with the restructuring, the Company estimates that it will incur aggregate restructuring charges of approximately $13.2 million, which will be recorded primarily in the fourth quarter of 2020, related to one-time termination severance payments and other employee-related costs, contract termination costs and a non-cash write-down of capitalized costs. The cash payments related to the personnel-related restructuring and contract termination charges will be paid during the fourth quarter of 2020 and the first quarter of 2021. The charges that the Company expects to incur in connection with the workforce reduction is subject to a number of assumptions, and actual results may differ materially. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the workforce reduction.

This Item 2.05 contains forward-looking statements, including, but not limited to, statements related to the expected costs associated with termination benefits and the financial impact of the reduction in force. These forward-looking statements are based on the Company's current expectations and inherently involve significant risks and uncertainties. The Company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to cost reduction efforts. In addition, the Company's workforce reduction costs may be greater than anticipated and the workforce reduction may have an adverse impact on the Company's development activities. A further description of the risks and uncertainties relating to the business of the Company is contained in the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020, filed with the Securities and Exchange Commission (the "SEC"), and the Company's subsequent current reports filed with the SEC. The Company undertakes no duty or obligation to update any forward-looking statements contained in this Item 2.05 as a result of new information, future events or changes in its expectations.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On October 29, 2020, the Company announced that Susannah Cantrell, Ph.D. will depart from her position as Executive Vice President and Chief Commercial Officer as of the close of business on Friday October 30, 2020. Due to the restructuring, Dr. Cantrell will be eligible to receive benefits upon her departure under, and consistent with, our previously disclosed Executive Severance Plan.

Item 7.01 Regulation FD Disclosure.

On October 29, 2020, the Company's management presented to investors using slides containing the information attached to this Current Report on Form 8-K as Exhibit 99.1 (the “Investor Presentation”) and is incorporated herein by reference.

Item 8.01 Other Events.

On October 29, 2020, the Company issued a press release announcing that it had completed an End-of-Review Type A meeting with the FDA regarding its New Drug Application for veverimer on October 20, 2020. The press release is attached to this Current Report on Form 8-K as Exhibit 99.2 (the "Press Release") and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Investor Presentation
99.2	Press Release
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: October 29, 2020

TRICIDA, INC.

By: /s/ Geoffrey M. Parker
Name: Geoffrey M. Parker
Title: Chief Financial Officer and Executive Vice President

Exhibit 99.1

Treating Metabolic Acidosis and Slowing the Progression of Chronic Kidney Disease

Investor Presentation – End-of-Review Type A Meeting Update
October 2020

TRICIDA

Forward Looking Statements

Any statements contained in this presentation or made during the accompanying oral presentation that are not statements of historical facts are forward-looking statements as defined under the Federal securities laws. Examples of such statements include our plans, beliefs, intentions, expectations and projections regarding, among other things: (i) the Company's expectations with regard to its interactions and communications with the FDA; (ii) its plans and expectations as to the pathway to approval of veverimer by the FDA and the design of its ongoing clinical trials; and (iii) expectations regarding financial runway. Any such forward-looking statements are based on our current expectations and assumptions, but are subject to a number of risks and uncertainties that could cause our actual future results to differ materially from our current expectations or those implied by the forward-looking statements. The risks and uncertainties that could adversely affect our forward-looking statements include, but are not limited to: (i) the timing of the FDA's approval of veverimer, if at all; (ii) the potential availability of the Accelerated Approval Program and the approvability of veverimer under that program; (iii) the Company's plans and expectations with regard to its interactions with the FDA, including the potential resubmission of an NDA for veverimer; (iv) the Company's plans and expectations for VALOR-CKD and future clinical and product development milestones; (v) the Company's financial projections and cost estimates; (vi) risks related to COVID-19; and (vii) risks associated with the Company's business prospects, financial results and business operations. These and other factors that may affect our future results and operations are identified and described in more detail in our filings with the Securities and Exchange Commission (the "SEC"), including the Company's most recent Annual Report filed on Form 10-K and our subsequently filed Quarterly Report(s) on Form 10-Q. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this presentation. Except as required by applicable law, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

Executive Summary

- Tricida has worked with FDA on accelerated approval for veverimer since 2017
- Prior to the End-of-Review Type A meeting, Tricida had 20 relevant FDA interactions all of which focused on development of veverimer based solely on the use of serum bicarbonate as the surrogate endpoint to enable accelerated approval and had not included a request for data on CKD progression from a near-term interim analysis of the VALOR-CKD trial
- Tricida has developed a deep understanding of the surrogate effect of serum bicarbonate and how it reasonably likely translates to clinical benefit
- In the End-of-Review Type A meeting, FDA provided feedback that Tricida believes introduces an additional requirement of data on CKD progression in addition to serum bicarbonate for accelerated approval
- Based on the endpoint and patient population, Tricida does not believe it can provide early information on CKD progression without compromising the integrity of VALOR-CKD
- Tricida is reorganizing the company to extend its financial runway in order to maximize its options for bringing veverimer to patients

20 Key FDA Interactions: No Prior Indication of a Requirement for CKD Progression Data for Accelerated Approval

- Feb 2017: FDA agreement on Accelerated Approval Program
- May 2017: FDA comments on TRCA-301 protocol to support accelerated approval
- Jul 2017: Meeting to discuss FDA's comments on TRCA-301 protocol
- Nov 2017: FDA response regarding proposed quantitative predictive model
- Mar 2018: Teleconference to discuss quantitative predictive model and VALOR-CKD study design
- May 2018: FDA response regarding quantitative predictive model
- Jun 2018: FDA response regarding draft VALOR-CKD protocol
- Sep 2018: FDA comments on VALOR-CKD protocol
- Jun 2019: Pre-NDA Meeting
- Aug 2019: Teleconference to discuss assessments of physical functioning in VALOR-CKD protocol
- Oct 2019: NDA Filing Letter
- Jan 2020: FDA comments on assessments of physical functioning in VALOR-CKD protocol
- Jan 2020: Mid-Cycle Communication Agenda
- Jan 2020: Mid-Cycle Meeting
- Apr 2020: Late-Cycle Meeting Background Package
- May 2020: Late-Cycle Meeting
- Jul 2020: FDA notification that deficiencies preclude discussion of labeling
- Jul 2020: FDA response regarding draft VALOR-CKD SAP
- Aug 2020: FDA Complete Response Letter
- Oct 2020: FDA preliminary comments for End-of-Review Type A meeting

SAP = Statistical Analysis Plan

Tricida Believes that Veverimer Is an Appropriate Candidate for Accelerated Approval

- End-stage renal disease (ESRD) is a serious disease and data support the link between metabolic acidosis and progression of CKD
- There is a high unmet need for an approved therapy
- Serum bicarbonate is a surrogate endpoint that is reasonably likely to predict clinical benefit in patients with CKD and metabolic acidosis based on data describing the pathophysiology of metabolic acidosis, data from interventional trials and observational cohort analyses, and the availability of two validated models that consistently describe the relationship between serum bicarbonate and the renal outcome measured in VALOR-CKD
- The TRCA-301 and TRCA-301E trials met all primary and secondary endpoints with high statistical significance
- Tricida believes veverimer's benefits outweigh the risk associated with use

Tricida has a Deep Understanding of the Surrogate Effect and How It Reasonably Likely Translates to Clinical Benefit

- Tricida focused the End-of-Review Type A meeting on the topic of whether the magnitude of treatment effect observed in TRCA-301/301E was reasonably likely to predict clinical benefit and support VALOR-CKD powering
  - Two predictive models consistently describe the association between serum bicarbonate values and the risk of CKD progression: the new time-dependent predictive model in > 24,000 US patients with metabolic acidosis and CKD shows 8.4% lower risk for each 1 mEq/L higher serum bicarbonate value
  - The predictive models support Tricida's belief that treatment effects ≥ 2 mEq/L are expected to provide clinical benefit in slowing CKD progression
  - The magnitude of the veverimer treatment effect in TRCA-301/301E is not best described by the between-group difference in the means because the data are not normally distributed. Between-group differences in medians are more appropriate in this case. The Week 52 median placebo-subtracted treatment effect was 3.15 mEq/L in TRCA-301E
  - Based on a median treatment effect of 3.15 mEq/L and the time-dependent predictive model, a hazard ratio of 0.76 is assumed for the ongoing VALOR-CKD confirmatory outcome study
  - We believe that VALOR-CKD is adequately designed and powered to confirm the clinical benefit of veverimer treatment. Using the 52-week median treatment effect from TRCA-301E (3.15 mEq/L), it has 87% power to show a 24% difference in primary endpoint events

Relevant FDA Comments in the CRL and July 30 Advice Letter

- CRL indicated that FDA was seeking additional data from at least one additional adequate and well-controlled study demonstrating the efficacy of veverimer for the treatment of metabolic acidosis associated with CKD
- In the CRL, the FDA expressed willingness to meet with Tricida to discuss options for approval of veverimer, including:
  - Completion of our ongoing confirmatory trial, VALOR-CKD, and if the trial is successful, submitting the results to support a conventional approval, or
  - Possibly conducting a pre-specified interim analysis of data from VALOR-CKD to support accelerated approval
- In a July 30, 2020 advice letter, the FDA suggested that a group sequential design for VALOR-CKD would be more efficient than Tricida's proposed adaptive design with unblinded sample size re-estimation

Tricida Now Believes FDA Will Require Data on CKD Progression for Accelerated Approval of Veverimer

- During the End-of-Review Type A meeting, Tricida presented information and made proposals that the company believes addressed the issues raised by the FDA in the CRL, including:
  - Information to support its belief that the data from the TRCA-301 and TRCA-301E trials were sufficient to support approval under the Accelerated Approval Program, including with respect to the magnitude and durability of the treatment effect of veverimer on the surrogate endpoint of serum bicarbonate and the applicability of the findings to the US population
  - A proposal to conduct an interim analysis of serum bicarbonate data from VALOR-CKD in ~500 patients treated for 12 months for purposes of confirming the treatment effect of veverimer observed in TRCA-301/301E and its applicability to the U.S. population and practice of medicine
  - If accepted by the FDA, Tricida believes this proposal would allow resubmission of the NDA for veverimer within a matter of months
- Based on feedback received during the meeting, Tricida now believes the FDA will require evidence of effect on CKD progression from a near-term interim analysis of VALOR-CKD for accelerated approval of veverimer and it is unlikely to rely solely on serum bicarbonate data
  - Tricida believes any requirement for early interim data on CKD progression is inconsistent with the Accelerated Approval Program
  - The Division did not request early interim data on CKD progression in the preliminary comments we received prior to the Type A meeting or in the CRL, nor at any time previously in the Accelerated Approval development program

Current Status

- As of October 28, 2020, the VALOR-CKD trial has randomized 1,208 of 1,600 patients with an average treatment duration of ~11 months and has accrued 42 of the ~500 required primary endpoint events
- Tricida is evaluating whether it is possible to provide the FDA with interim data on CKD progression from VALOR-CKD, however:
  - Tricida believes that based on the severity of kidney disease in its patient population and the double-blind, placebo controlled, time-to-event design of our outcomes trial, unblinded interim analyses of data on CKD progression are not appropriate or feasible
  - Tricida believes its current development program meets the requirements for accelerated approval
  - Tricida is committed to protecting the integrity of the VALOR-CKD trial, which was intended as the confirmatory outcomes study for approval of veverimer under the Accelerated Approval Program
- Tricida plans to wait for formal meeting minutes from the FDA related to the Type A meeting prior to determining how to proceed with obtaining regulatory approval for veverimer. Tricida expects to receive the formal minutes within 30 days from the meeting

Metabolic Acidosis in CKD – An Unmet Need

Managing Risk Factors of CKD Progression

Good management to prevent nutritional decline, functional decline, as well as acidosis, can help slow down CKD progression

Clinical Practice Guidelines

KDIGO & KDOQI recommend treatment for people with CKD whose serum bicarbonate is < 22 mEq/L. *There are currently no approved treatments in the US*

Available Unapproved Supplements

Sodium- & potassium-containing alkali salts are available to treat MA, however are used only in < 3% of CKD patients with serum bicarbonate levels < 22 mEq/L (Dobre, 2013)

Limitations of Current Supplements

Common comorbidities such as hypertension, heart failure, edematous states & hyperkalemia are absolute or relative contraindications to treatments that ↑ sodium &/or potassium intake

The Goals of Treatment of Metabolic Acidosis are to:

1. Correct chronic systemic acidemia
2. Decrease protein catabolism caused by skeletal muscle proteolysis
3. Reduce bone demineralization
4. Prevent protein-energy wasting & nutritional decline
5. Slow the progression of CKD

A significant unmet need exists for additional treatment options for people with CKD and metabolic acidosis. A treatment that is safe and that effectively treats metabolic acidosis without introducing unwanted ions, would address this need

Bushinsky, AJKD, 2019. Dobre et al., AJKD, 2013. Kovesdy et al., Int Urol Nephrol, 2016. KDIGO CKD Work Group, Kidney Inter, Suppl 2013. Eknoyan G et al., Am J Kidney Dis., 2003.

Tricida Believes Veverimer's Benefits Outweigh the Risks Associated with Use

Veverimer – Potential Benefits

Serum Bicarbonate:

- ✓ Rapid onset of effect
- ✓ Predictable offset of effect
- ✓ Evidence of efficacy over 1 year of treatment

Physical functioning:

- ✓ *KDQOL-PFD:* Significant improvement in score at week 52 from baseline in the veverimer group vs. the placebo-treated group [11.42 vs. -0.71 points, $p < 0.0001$], exceeding the 3 to 5 point minimally important clinical difference
- ✓ *Chair stand test:* There was a significant decline in the mean time to complete the test at week 52 vs. baseline in the veverimer group vs. the placebo group [-4.28 vs. -1.42 seconds, $p < 0.0001$], exceeding the 1.7 second minimally important clinical difference

Veverimer – Potential Risks

The safety of up to 1 year of treatment with veverimer has been studied in a complex population of patients with Stage 3 − 4 CKD and metabolic acidosis:

- ➢ Veverimer was well tolerated with high treatment adherence and an excellent safety profile
- ➢ Percentage of subjects with SAEs or treatment discontinuations due to AEs was low overall, but higher in the placebo group versus the veverimer group.
  - ➢ The only AEs reported in ≥ 5% of subjects in which the incidence was higher (> 1% difference) for veverimer than for placebo were *nontreatment limiting diarrhea and flatulence*, typically lasting a few days
- ➢ No evidence of off-target binding
- ➢ Negligible risk of veverimer involvement in clinically significant drug-drug interactions

Given the findings of the surrogate endpoint of serum bicarbonate, as well as the improvements observed in how subjects felt and functioned, the benefits of treatment with veverimer outweigh the risks associated with use

Wesson et al., Lancet 2019; 393 1417-27. Wesson et al., Lancet 2019; 394: 396-406.

Organizational Update and Financial Position

- Tricida is re-organizing the company to extend its financial runway in order to maximize its options for bringing veverimer to patients
  - Significantly reducing its headcount
  - Tricida will discuss its commitments with vendors and contract service providers to potentially provide additional financial flexibility
- Cash and cash equivalents at September 30, 2020 were ~$375 million
  - Tricida has $75 million principal amount of debt with Hercules which is scheduled to be amortized from April 2021 to April 2023
  - Tricida has $200 million principal amount of 3.5% Convertible Senior Notes which mature in May 2027

THANK YOU

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Supplemental Information

Two Independent Models Based on Observational Data Consistently Describe the Association between Serum Bicarbonate and CKD Progression

	Single Baseline Model	Time-Dependent Model
Data Source	Sunnybrook Hospital, Canada	OptumLabs Data Warehouse, U.S.
Sample Size (N)	2,378	24,384
Population	CKD G3 – 5	CKD G3 – 5 and metabolic acidosis
Explanatory variable	Single baseline serum bicarbonate value at cohort entry	Time-dependent, within-patient change in serum bicarbonate
Outcome	ESRD or a ≥ 40% decline in eGFR	ESRD or a confirmed ≥ 40% decline in eGFR
Median number of bicarbonate values	1	10
Median duration of follow-up	439 days	1,362 days
Hazard Ratio per 1 mEq/L serum bicarbonate	0.925 (0.904, 0.947)	0.916 (0.912, 0.921)

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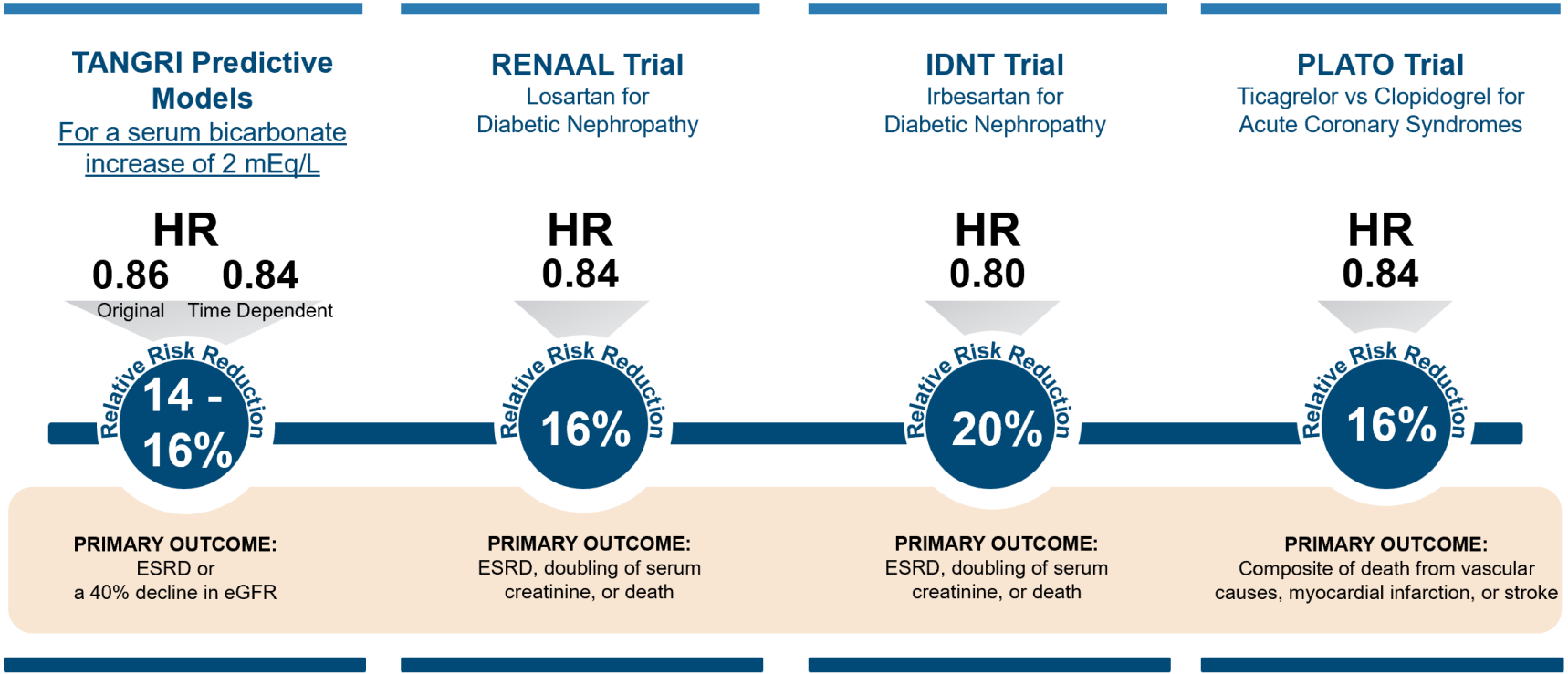
Tangri et al., NKF SCM, 2018. Data on file.

Randomized Controlled Trials Show Clinical Benefit of Group Mean Treatment Effects of 2 – 3 mEq/L

- A meta-analysis of 14 randomized controlled trials (N=1,394) found that increasing serum bicarbonate resulted in slower decline of kidney function
  - Average increase in bicarbonate
    - 3.3 mEq/L (95% CI: 2.4 – 4.3) in a random effects model
    - 2.3 mEq/L (95% CI: 2.1 – 2.5) in a fixed effects model
- Net effect on eGFR decline = -3.28 mL/min/yr (95% CI: -4.42,-2.14; 13 trials)
- Hazard ratio (HR) for ESRD = 0.32 (95% CI: 0.18, 0.56; 4 trials)

Navaneethan et al, CJASN, 2019.

A Treatment Effect of ≥ 2 mEq/L is Reasonably Likely to Predict Clinical Benefit with a HR Consistent with Other Approved Cardio-Renal Drugs



HR = Hazard Ratio. Tangri et al., NKF SCM, 2018. Data on file. Brenner et al., NEJM, 2001. Lewis et al., NEJM, 2001. Wallentin et al., NEJM, 2009.

Magnitude of Treatment Effect Observed in TRCA-301/301E Should be Described by the Difference in Medians

- Post-hoc analysis of change from baseline in serum bicarbonate from TRCA-301/301E showed that the data were not normally distributed
  - Shapiro-Wilk test ($p < 0.05$) at Week 12 and Week 52
- Thus, the between-group difference of the medians, rather than means, are a better descriptor of the magnitude of change from baseline in serum bicarbonate (i.e., the treatment effect) and therefore we believe are more appropriate for use in estimating the power of the ongoing

Median Change from Baseline in Serum Bicarbonate (mEq/L)

Timepoint	Veverimer	Placebo	Difference	P-value*
Week 12	4.70	1.50	3.20	<0.0001
Week 52	5.40	2.25	3.15	0.0001

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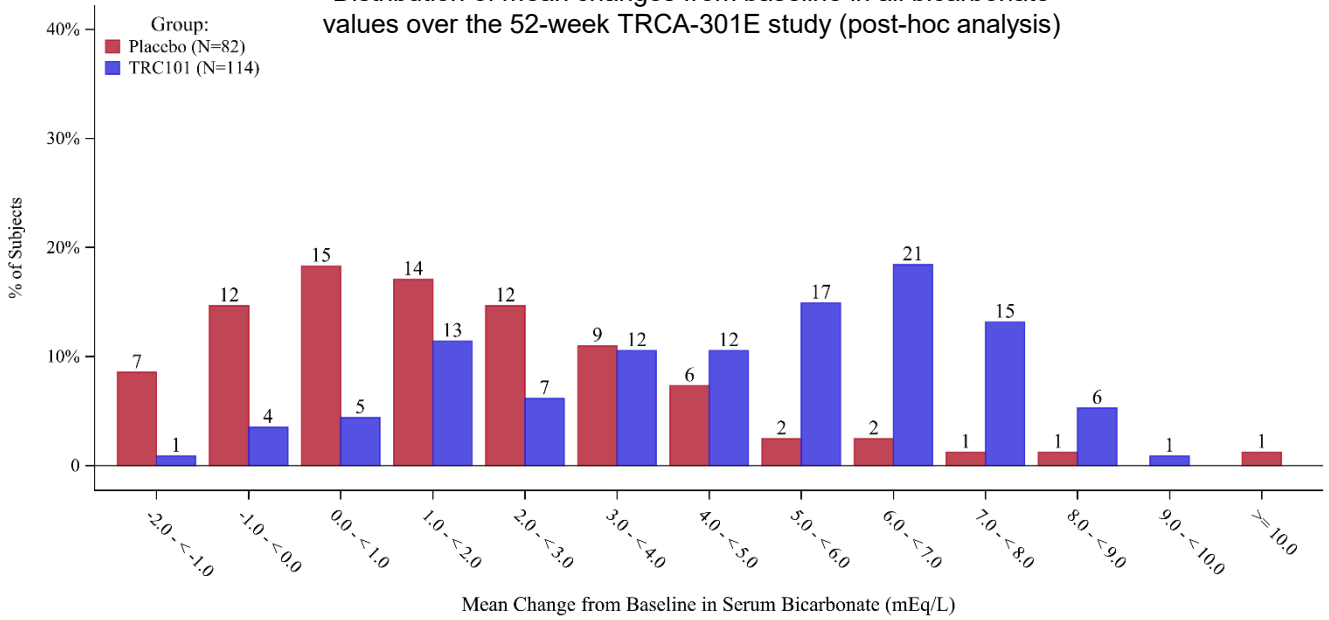
*post hoc ANCOVA using ranks. Data on file.

Magnitude of Effect: Patients Receiving Veverimer Are Reasonably Likely to Derive Benefit

Substantially more patients on veverimer than placebo have large increases in serum bicarbonate (e.g., >3, >4, >5 mEq/L)

Distribution of mean changes from baseline in all bicarbonate values over the 52-week TRCA-301E study (post-hoc analysis)



Proportion of Patients with Mean Increase ≥ 5 mEq/L

52.6% (60 of 114): Veverimer
8.5% (7 of 82): Placebo

Proportion of Patients with Mean Increase ≥ 4 mEq/L

63.2% (72 of 114): Veverimer
15.9% (13 of 82): Placebo

Proportion of Patients with Mean Increase ≥ 3 mEq/L

73.7% (84 of 114): Veverimer
26.8% (22 of 82): Placebo

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Data on file.

Exhibit 99.2

FOR IMMEDIATE RELEASE

Tricida Provides Update on FDA Interactions

SOUTH SAN FRANCISCO, Calif., October 29, 2020 — Tricida, Inc. (Nasdaq: TCDA), a pharmaceutical company focused on the development and commercialization of its investigational drug candidate, veverimer (TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis in patients with chronic kidney disease (CKD), announced today that it held an End-of-Review conference as a Type A meeting with the Division of Cardiology and Nephrology of the U.S. Food and Drug Administration (FDA) on October 20, 2020. This meeting followed a Complete Response Letter (CRL) that was received by the company on August 21, 2020 for the veverimer NDA that was under review by the FDA through the Accelerated Approval Program.

In Tricida's meeting package before the Type A meeting, the company included a proposal to conduct an interim analysis of serum bicarbonate data from VALOR-CKD in ~500 patients treated for 12 months for purposes of confirming the treatment effect of veverimer observed in the TRCA-301/301E trials and its applicability to the U.S. population and practice of medicine. If accepted by the FDA, Tricida believed this proposal would allow resubmission of the NDA for veverimer within a matter of months. Based on feedback during the Type A meeting, Tricida 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. The company's ongoing VALOR-CKD trial was designed to be a confirmatory trial to demonstrate the effect of veverimer on slowing CKD progression following accelerated approval. Based on the primary endpoint and patient population in VALOR-CKD, Tricida does not believe it can provide information on CKD progression from a near-term interim analysis of the VALOR-CKD trial without compromising the integrity of the ongoing trial.

The company believes any requirement for early interim CKD progression data in addition to surrogate data at the time of accelerated approval is inconsistent with the intent of the Subpart H regulation. Indeed, prior to the End-of-Review Type A meeting, over nearly four years, Tricida's discussions with the FDA 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. Tricida has developed a deep understanding of the surrogate endpoint of an increase in serum bicarbonate and how it reasonably likely translates to clinical benefit. The company continues to believe that its current development program for veverimer is an appropriate candidate for accelerated approval based on (1) the seriousness of end-stage renal disease (ESRD), (2) the high unmet need for an approved therapy, and (3) data supporting the link between metabolic

acidosis and progression of CKD, including data describing the pathophysiology of metabolic acidosis, published data from multiple interventional trials and observational cohort analyses, and the availability of two validated models that consistently describe the relationship between serum bicarbonate and the renal outcome that is being measured in VALOR-CKD.

“We are surprised by the feedback received from the FDA during the Type A meeting” said Gerrit Klaerner, Ph.D., Tricida’s Chief Executive Officer and President. “The introduction of a requirement for data on the effect of veverimer on renal disease progression to support initial accelerated approval clearly represents a major setback in the timeline for the development of veverimer. We remain dedicated to bringing veverimer to patients with CKD and metabolic acidosis who currently have no FDA-approved therapy for their disease.”

Tricida 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. The company expects to receive the formal minutes within 30 days from the meeting.

Organizational Update and Financial Position

Tricida is re-organizing the company to extend its financial runway in order to maximize the options for bringing veverimer to patients. The company 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. This reduction in headcount will reduce Tricida’s annual operating costs by approximately $25 million.

Cash and cash equivalents as of September 30, 2020 were approximately $375 million. Tricida currently has $75 million principal amount of debt with Hercules which is scheduled to be amortized from April 2021 to April 2023 and has $200 million in outstanding principal amount of 3.5% Convertible Senior Notes which mature in May 2027.

Tricida Conference Call Information

Tricida will host a conference call and webcast at 8:00 am Eastern Time today to discuss the preliminary feedback from its FDA interactions and future plans. The webcast, including slides, or conference call may be accessed as follows:

Tricida Conference Call

Thursday, October 29, 2020

8:00 am Eastern Time

Webcast:	IR.Tricida.com
Dial-in:	**(877) 377-5478**
International:	(629) 228-0740
Conference ID:	**9786643**

A replay of the webcast will be available on Tricida’s website approximately two hours following the completion of the call and will be available for up to 90 days following the presentation.

About Tricida

Tricida, Inc. is a pharmaceutical company focused on the development and commercialization of its investigational drug candidate, veverimer (TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis in patients with CKD. There are no FDA-approved treatments for chronic metabolic acidosis, a condition commonly caused by CKD that is believed to accelerate the progression of kidney deterioration. It is estimated to pose a health risk to approximately three million patients with CKD in the United States.

For more information about Tricida, please visit www.Tricida.com.

Cautionary Note on Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as “projects,” “believes,” “anticipates,” “plans,” “expects,” “intends,” “may,” “will,” “could,” “should,” “would,” and similar words and expressions are intended to identify forward-looking statements. Any statements contained herein which do not describe historical facts, including the Company’s expectations with regard to its interactions and communications with the FDA, its plans and expectations as to the pathway to approval of veverimer by the FDA and the design of its ongoing clinical trials, and expectations regarding financial runway are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements. Such risks and uncertainties include, without limitation, the timing of the FDA’s approval of veverimer, if at all; the potential availability of the Accelerated Approval Program and the approvability of veverimer under that program; the Company’s plans and expectations with regard to its interactions with the FDA, including the potential resubmission of an NDA for veverimer; the Company’s plans and expectations for VALOR-CKD and future clinical and product development milestones; the Company’s financial projections and cost estimates; and risks associated with the Company’s business prospects, financial results and business operations.

These and other factors that may affect the Company’s future business prospects, results and operations are identified and described in more detail in the Company’s filings with the Securities and Exchange Commission (the “SEC”), including the Company’s most recent Annual Report filed on Form 10-K and the subsequently filed Quarterly Report(s) on Form 10-Q. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Except as required by applicable law, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

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