

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

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

Date of Report (Date of earliest event reported): February 25, 2021



**TRICIDA, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**001-38558**

(Commission File Number)

**46-3372526**

(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**

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
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 2.02 Results of Operations and Financial Condition.**

On February 25, 2021, Tricida, Inc. (the "Company"), issued a press release announcing its financial results for its fourth quarter and full-year ended December 31, 2020. A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. On February 22, 2021, the Company announced that it will host a conference call and webcast at 4:30 pm Eastern Time, on February 25, 2021, during which the Company will discuss its financial results for the fourth quarter and full-year ended December 31, 2020 and report its business progress.

**Item 8.01 Other Events.**

On February 25, 2021, Tricida, Inc., issued a press release announcing that it had received an Appeal Denied Letter from the Office of New Drugs of the FDA to its Formal Dispute Resolution Request.

The press release is attached herewith as Exhibit 99.2 and is incorporated into this Item 8.01 by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release, Tricida Announces Fourth Quarter and Full Year 2020 Financial Results</a>
99.2	<a href="#">Press Release, FDRR Update</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURE**

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

Dated: February 25, 2021

**TRICIDA, INC.**

By: /s/ Geoffrey M. Parker

Name: Geoffrey M. Parker

Title: Chief Operating Officer, Chief Financial Officer and Executive Vice President

**FOR IMMEDIATE RELEASE****Tricida Announces Fourth Quarter and Full Year 2020 Financial Results**

SOUTH SAN FRANCISCO, Calif., February 25, 2021 — 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 financial results for the fourth quarter and year ended December 31, 2020 and provided an update on key initiatives.

**Recent Events**

- As announced separately today, Tricida has received an Appeal Denied Letter (ADL) from the Office of New Drugs (OND) of the U.S. Food and Drug Administration (FDA) in response to its Formal Dispute Resolution Request (FDRR).
- Tricida continues to effectively execute on VALOR-CKD trial recruitment and conduct. As of February 22, 2021, the VALOR-CKD trial has randomized 1,433 of 1,600 subjects with an average treatment duration of approximately one year and has accrued 69 of the 511 required subjects with positively adjudicated primary endpoint events.
- Tricida announced that Geoffrey Parker, Chief Financial Officer and Executive Vice President has been promoted to the newly created role of Chief Operating Officer, Chief Financial Officer and Executive Vice President. In his expanded role, Mr. Parker will continue to lead all finance and accounting activities and additionally focus on corporate and business development strategies.

**2020 Key Events**

Tricida's key events and activities in 2020 include:

- Received a Complete Response Letter (CRL) for its veverimer New Drug Application (NDA) in August 2020;
- Held an End-of-Review Type A meeting in response to the CRL in October 2020;
- Submitted the FDRR to the OND in December 2020;
- Restructured the company in the second half of 2020 in order to maximize the options for bringing veverimer to patients;

- Presented or published 20 peer-reviewed posters or articles that highlight veverimer, the serious complications of metabolic acidosis and its economic burden to the healthcare system;
- Engaged with 126 payers representing approximately 310 million lives to evaluate coverage of veverimer, if approved, provide information about the design and results of our health economic study and share veverimer clinical trial data;
- Expanded metabolic acidosis disease education and awareness through the sponsorship of Continuing Medical Education (CME) programs, and enhanced educational materials available through the [MetabolicAcidosisInsights.com](https://www.MetabolicAcidosisInsights.com) website;
- Continued successful execution on its global IP strategy, resulting in the allowance of a U.S. patent application that, upon issuance in 2021 will extend protection for veverimer to 2038 in the U.S., and the issuance of an additional 126 patents in 47 different countries, including Australia, China, Israel, Japan, Russia and numerous European and European extension states; and
- Issued, in May 2020, \$200 million aggregate principal amount of 3.50% convertible senior notes due 2027, securing additional capital to fund operations.

“We accomplished a great deal in 2020 but were obviously disappointed that we could not launch veverimer as the first and only FDA-approved treatment for chronic metabolic acidosis in patients with CKD,” said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. “We will now focus on the VALOR-CKD trial to generate additional data prior to the end of 2022.”

### **Upcoming Milestones**

- Anticipate the first VALOR-CKD renal outcomes trial interim analysis for early stopping for efficacy in the second half of 2021 when 150 primary renal endpoint events are expected to have accrued. A primary endpoint event in the VALOR-CKD trial is defined as renal death, end-stage renal disease (ESRD) or a confirmed  $\geq 40\%$  reduction in estimated glomerular filtration rate (eGFR), also known as DD40. If the independent unblinded Interim Analysis Committee does not recommend stopping the trial early for efficacy, we will receive no information from this interim analysis.
- Anticipate the second VALOR-CKD renal outcomes trial interim analysis for early stopping for efficacy in mid-2022 when 250 primary renal endpoint events are expected to have accrued. If the independent unblinded Interim Analysis Committee does not recommend stopping the trial early for efficacy, we will receive no information from this interim analysis.
- Prior to the end of 2022, the company will also evaluate options with a focus on obtaining additional data from the VALOR-CKD trial on the effects of veverimer on (1) CKD progression; (2) physical functioning; and (3) serum bicarbonate. These options include the possibility of stopping the trial early for administrative reasons, which would allow analysis of the data using all alpha remaining at that time.

### **Financial Results for the Three Months and Year Ended December 31, 2020**

Research and development expense was \$27.3 million and \$40.7 million for the three months ended December 31, 2020 and 2019, respectively, and \$148.4 million and \$133.0 million for the years ended December 31, 2020 and 2019, respectively. The decrease in research and development expense for the three months ended December 31, 2020 compared to the prior year was primarily due to a decrease in activities in connection with our veverimer clinical development program related to manufacturing process optimization and the manufacturing of drug substance and lower personnel costs. The increase in research and development expense for the year ended December 31, 2020 compared to the prior year was primarily due to increased activities in connection with our veverimer clinical development program related to manufacturing process optimization and the manufacturing of drug substance, partially offset by lower personnel costs.

General and administrative expense was \$21.8 million and \$17.5 million for the three months ended December 31, 2020 and 2019, respectively, and \$103.0 million and \$45.8 million for the years ended December 31, 2020 and 2019, respectively. The increase in general and administrative expense for the three months ended December 31, 2020 compared to the prior year was primarily due to restructuring costs including one-time termination severance payments and contract termination costs, partially offset by lower pre-commercialization and other administrative costs due to a decrease in activities in connection with our veverimer clinical development program. The increase in general and administrative expense for the year ended December 31, 2020 compared to the prior year was primarily due to increased pre-commercialization and associated administrative activities in connection with our veverimer clinical development program and restructuring costs including one-time termination severance payments and contract termination costs.

Net loss was \$54.8 million (non-GAAP net loss of \$33.0 million) and \$58.2 million (non-GAAP net loss of \$47.3 million) for the three months ended December 31, 2020 and 2019, respectively, and \$264.8 million (non-GAAP net loss of \$214.4 million) and \$176.8 million (non-GAAP net loss of \$147.7 million) for the years ended December 31, 2020 and 2019, respectively. Net loss per basic and diluted share was \$1.09 and \$1.17 for the three months ended December 31, 2020 and 2019, respectively, and \$5.29 and \$3.72 for the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, cash, cash equivalents and investments were \$332.3 million.

### **Financial Guidance**

Tricida currently has the financial resources to fund its operations into at least mid-2022, prior to modifying any of its material agreements. Discussions are ongoing to modify certain of these agreements and, if successful, would extend the company's financial resources beyond mid-2022. Tricida plans to obtain additional data on the effect of veverimer on (1) CKD progression; (2) physical functioning; and (3) serum bicarbonate within the time frame of our existing capital resources.

## Tricida Conference Call Information

Tricida will host its Fourth Quarter Financial Results and Business Update Conference Call and webcast today at 4:30 pm Eastern Time. The webcast or conference call may be accessed as follows:

**Tricida Conference Call**  
**Thursday, February 25, 2021**  
**4:30 pm Eastern Time**

**Webcast:** [IR.Tricida.com](http://IR.Tricida.com)

**Dial-In:** (800) 773-2954

International: (847) 413-3731

**Conference ID:** 50111253

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 (also known as TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis in patients with CKD. Tricida is currently conducting a renal outcomes clinical trial, VALOR-CKD, to determine if veverimer slows CKD progression in patients with metabolic acidosis associated with CKD. There are no FDA-approved treatments for chronic metabolic acidosis. Metabolic acidosis is 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 [Tricida.com](http://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. These forward-looking statements include, but are not limited to, all of the statements under the heading "Upcoming Milestones" and other statements, including the Company's plans and expectations for VALOR-CKD, its interactions and communications with the FDA, its plans and expectations as to the pathway to approval of veverimer by the FDA, if at all, including the potential availability of the Accelerated Approval Program, and its 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 future clinical and product development milestones; the Company's contractual and financial obligations to our key suppliers and vendors; the Company's financial projections and cost estimates; risks associated with the COVID-19 pandemic; 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 (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.

(Financial Tables to Follow)

Tricida, Inc.

Condensed Balance Sheets  
(Unaudited)  
(In thousands)

	December 31, 2020	December 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 137,857	\$ 18,574
Short-term investments	171,670	289,424
Prepaid expenses and other current assets	4,488	4,744
Total current assets	<u>314,015</u>	<u>312,742</u>
Long-term investments	22,757	46,980
Property and equipment, net	1,112	2,728
Operating lease right-of-use assets	13,801	9,376
Total assets	<u>\$ 351,685</u>	<u>\$ 371,826</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,508	\$ 5,911
Current operating lease liabilities	2,079	1,072
Accrued expenses and other current liabilities	28,671	32,780
Total current liabilities	<u>34,258</u>	<u>39,763</u>
Term Loan, net	76,638	58,374
Convertible Senior Notes, net	118,670	—
Non-current operating lease liabilities	13,046	8,783
Other long-term liabilities	202	1,023
Total liabilities	<u>242,814</u>	<u>107,943</u>
Stockholders' equity:		
Preferred stock	—	—
Common stock	50	50
Additional paid-in capital	742,555	632,647
Accumulated other comprehensive income (loss)	64	193
Accumulated deficit	<u>(633,798)</u>	<u>(369,007)</u>
Total stockholders' equity	<u>108,871</u>	<u>263,883</u>
Total liabilities and stockholders' equity	<u>\$ 351,685</u>	<u>\$ 371,826</u>

Tricida, Inc.

Statements of Operations and Comprehensive Loss  
(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Years Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 27,283	\$ 40,653	\$ 148,417	\$ 133,028
General and administrative	21,766	17,463	102,983	45,796
Total operating expenses	49,049	58,116	251,400	178,824
Loss from operations	(49,049)	(58,116)	(251,400)	(178,824)
Other income (expense), net	621	1,407	5,016	7,663
Interest expense	(6,364)	(1,554)	(18,407)	(5,744)
Loss before income taxes	(54,792)	(58,263)	(264,791)	(176,905)
Income tax benefit (expense)	(50)	92	—	92
Net loss	(54,842)	(58,171)	(264,791)	(176,813)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale investments, net of tax	(368)	(293)	(129)	346
Total comprehensive loss	\$ (55,210)	\$ (58,464)	\$ (264,920)	\$ (176,467)
Net loss per share, basic and diluted	\$ (1.09)	\$ (1.17)	\$ (5.29)	\$ (3.72)
Weighted-average number of shares outstanding, basic and diluted	50,186,615	49,620,063	50,027,735	47,521,237

Tricida, Inc.

**GAAP to non-GAAP reconciliations**  
**(Unaudited)**  
*(In thousands)*

A reconciliation between net loss on a GAAP basis and on a non-GAAP basis is as follows:

	Three Months Ended December 31,		Years Ended December 31,	
	2020	2019	2020	2019
GAAP net loss, as reported	\$ (54,842)	\$ (58,171)	\$ (264,791)	\$ (176,813)
Adjustments:				
Non-cash operating lease costs	207	318	845	964
Accretion of Term Loan and Convertible Senior Notes	2,915	609	8,258	2,173
Stock-based compensation	7,655	9,415	28,298	25,168
Changes in fair value of compound derivative liability	(49)	557	(775)	816
Restructuring costs	11,089	—	13,749	—
Total adjustments	21,817	10,899	50,375	29,121
Non-GAAP net loss	\$ (33,025)	\$ (47,272)	\$ (214,416)	\$ (147,692)

**Use of Non-GAAP Financial Measures**

We supplement our financial statements presented on a GAAP basis by providing additional measures which may be considered “non-GAAP” financial measures under applicable Securities and Exchange Commission rules. We believe that the disclosure of these non-GAAP financial measures provides our investors with additional information that reflects the amounts and financial basis upon which our management assesses and operates our business. These non-GAAP financial measures are not in accordance with generally accepted accounting principles and should not be viewed in isolation or as a substitute for reported, or GAAP, net loss and diluted earnings per share, and are not a substitute for, or superior to, measures of financial performance performed in conformity with GAAP.

“Non-GAAP net loss” is not based on any standardized methodology prescribed by GAAP and represents GAAP net loss adjusted to exclude (1) non-cash operating lease costs, (2) accretion of Term Loan and Convertible Senior Notes, (3) stock-based compensation, (4) changes in fair value of compound derivative liability, and (5) restructuring costs (cash and non-cash), in reconciling of our GAAP to Non-GAAP net loss. Non-GAAP financial measures used by Tricida may be calculated differently from, and therefore may not be comparable to, non-GAAP measures used by other companies.

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Contact:  
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Tricida, Inc.  
Senior Vice President of  
Investor Relations and Communications  
IR@Tricida.com



**FOR IMMEDIATE RELEASE**

**Tricida Provides Update on FDA Interactions**

*Tricida Has Received an Appeal Denied Letter from the Office of New Drugs of the FDA in Response to its Formal Dispute Resolution Request*

SOUTH SAN FRANCISCO, Calif., February 25, 2021 — Tricida, Inc. (Nasdaq: TCDA), a pharmaceutical company focused on the development and commercialization of its investigational drug candidate, veverimer, a non-absorbed, orally-administered polymer designed to treat metabolic acidosis in patients with chronic kidney disease (CKD), today provided an update on its U.S. Food and Drug Administration (FDA) interactions.

Tricida has 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. While the FDRR was focused on whether the magnitude and durability of serum bicarbonate change seen in the TRCA-301/TRCA-301E trial is reasonably likely to predict clinical benefit in the treatment of metabolic acidosis in patients with CKD, the OND's decision additionally addressed other deficiencies identified in the Complete Response Letter (CRL), which Tricida received in August 2020. The additional issues addressed included the reliability of the data from the TRCA-301/TRCA-301E trial due to the disproportionate impact of data from a single high-enrolling clinical site on the trial's results and the applicability of the trial results to the U.S. patient population given that the majority of the subjects in the study were enrolled in sites outside of the United States or were in regions that the FDA does not consider "U.S.-like," such as Eastern Europe.

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. The FDA did not raise any concerns related to its completed inspection of the highest-enrolling clinical trial site and there was no FDA Form 483 issued. Also, while the OND did not suggest that there was a specific unblinding issue in the TRCA-301/TRCA-301E trial, the OND noted concerns around adequate blinding and that, while the measures in place to protect the study blind in the TRCA-301/TRCA-301E trial were reasonable, they may not have optimally protected the blind.

Although the ADL provides greater clarity on the potential path for approval of veverimer through the Accelerated Approval Program, Tricida believes the timeline to meet the requirements for accelerated approval as suggested in the ADL may not result in the most rapid development path for veverimer. For example, the OND suggested that Tricida meet with the Division of Cardiology and Nephrology (the Division) to discuss submission of 52-week serum bicarbonate results from the fully randomized VALOR-CKD trial and that such submission should include a substantial proportion of U.S. and "U.S.-like" patients. The OND also indicated that, if the results of this trial were to demonstrate a meaningfully larger treatment effect on serum bicarbonate than seen in the TRCA-301/TRCA-301E trial, results from VALOR-CKD, along with the results from the TRCA-301/TRCA-301E trial, could address the deficiencies identified in the CRL. However, the OND noted that whether these data would support accelerated approval would remain a review issue and therefore would be subject to the Division's assessment of the adequacy of the magnitude of increase in serum bicarbonate. Moreover, based on the concerns expressed, we believe that the FDA could require an additional trial or trials to confirm the magnitude, durability of effect or applicability to the U.S. population for resubmission of the veverimer NDA through the Accelerated Approval Program.

Given the feedback provided by the FDA in the ADL, Tricida intends to continue the VALOR-CKD trial without further modifications at the present time with consideration of both the accelerated and traditional approval pathways. Tricida's planned interim analyses in the VALOR-CKD trial could result in early stopping for efficacy and resubmission of the NDA through a traditional approval pathway with a potential indication of treatment of metabolic acidosis to slow CKD progression. Tricida is also evaluating several options with respect to the VALOR-CKD trial

that are focused on obtaining additional data prior to the end of 2022 on the effect of veverimer on (1) CKD progression; (2) physical functioning; and (3) serum bicarbonate. These options include the possibility of stopping the trial early for administrative reasons, which would allow analysis of the data using all alpha remaining at that time. In any event, Tricida believes data from VALOR-CKD will be very important in furthering the understanding of the regulatory path for approval of veverimer.

“The feedback that we received from OND makes clear that the results from the TRCA-301/TRCA-301E trial alone will not support accelerated approval of veverimer,” said Gerrit Klaerner, Ph.D., Tricida’s Chief Executive Officer and President. “We certainly hear and understand the need for additional data and believe that the VALOR-CKD trial is the best near-term source to provide that information.”

### **Tricida Conference Call Information**

Tricida will host its Fourth Quarter Financial Results and Business Update Conference Call and webcast today at 4:30 pm Eastern Time. The webcast or conference call may be accessed as follows:

#### **Tricida Conference Call**

**Thursday, February 25, 2021**

**4:30 pm Eastern Time**

<b>Webcast:</b>	IR.Tricida.com
<b>Dial-in:</b>	<b>(800) 773-2954</b>
International:	(847) 413-3731
<b>Conference ID:</b>	<b>50111253</b>

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 the VALOR-CKD Clinical Trial**

The ongoing VALOR-CKD trial is a renal outcomes clinical trial designed to determine if veverimer slows CKD progression in patients with metabolic acidosis associated with CKD. The VALOR-CKD trial is a randomized, double-blind, placebo-controlled, time-to-event trial. The primary endpoint in VALOR-CKD is defined as a composite of renal death, end-stage renal disease (ESRD) or a confirmed  $\geq 40\%$  reduction in estimated glomerular filtration rate (eGFR)

(DD40). We anticipate randomizing approximately 1,600 subjects in VALOR-CKD and the trial is currently designed to terminate when the independent blinded Clinical Endpoint Adjudication Committee has positively adjudicated 511 subjects with primary efficacy endpoint events, which is anticipated to occur in the first half of 2024. The VALOR-CKD trial also includes two interim analyses for early stopping for efficacy after the accrual of 150 primary endpoint events, which is anticipated in the second half of 2021, and 250 primary endpoint events, which is anticipated in mid-2022. The VALOR-CKD trial also includes, as its first two secondary efficacy endpoints, evaluation of the effect of veverimer versus placebo after one year of treatment on patient-reported and objective measures of physical functioning, using the Kidney Disease and Quality of Life Physical Functioning Survey, or KDQOL Physical Functioning Survey, and the Repeated Chair Stand test, respectively. Although not part of any efficacy endpoints, the VALOR-CKD trial will also provide information regarding the change from baseline in serum bicarbonate in veverimer and placebo-treated subjects.

In November 2020, following the receipt of the CRL, Tricida revised the protocol for the VALOR-CKD trial based on feedback from the FDA in a July 2020 advice letter as well as additional work to understand both the hazard ratio and the anticipated serum bicarbonate effect of veverimer. In collaboration with Dr. Navdeep Tangri, M.D., Ph.D., of the University of Manitoba, Canada, Tricida developed a Time-Dependent Predictive Model in a cohort of more than 24,000 U.S. patients with metabolic acidosis and CKD. The results from this model show an 8.4% lower risk of CKD progression for each 1 mEq/L increase in serum bicarbonate. In addition, we believe the magnitude of the veverimer treatment effect in the TRCA-301/TRCA-301E trial is best described by the between-group difference in the medians, rather than the difference in the LS means, as the data are not normally distributed. The Week 52 median placebo-subtracted treatment effect in the TRCA-301/TRCA-301E trial was an increase in serum bicarbonate of 3.15 mEq/L. Using the Time-dependent Predictive Model, we predict that a median treatment effect of 3.15 mEq/L is associated with a hazard ratio of 0.76 for the VALOR-CKD renal outcome trial. Thus, with a sample size of 1,600 subjects, the trial has 87% power to show a 24% difference in primary endpoint events. These current assumptions for the powering of the VALOR-CKD trial were not considered by the OND in their response to the FDRR, and we have not yet received FDA comments on this revised draft protocol.

Tricida initiated enrollment in the VALOR-CKD trial in the fourth quarter of 2018 and has established sites throughout North America, Europe, Latin America and Asia-Pacific. As of February 22, 2021, the VALOR-CKD trial has randomized 1,433 of 1,600 subjects with an average treatment duration of approximately one year and has accrued 69 subjects with positively adjudicated primary endpoint events. In November 2020, based on feedback from the FDA, recruitment for VALOR-CKD was closed in all regions except for the United States, Canada and Western Europe. At the end of recruitment, Tricida anticipates approximately 67%

of subjects to be enrolled at Eastern European sites, 19% at US, Western European and Canadian sites, 7% at Latin American sites, and 7% at sites in the Asia-Pacific region. Tricida's goal is to complete enrollment in the trial by the end of 2021; to meet this goal it may need to reopen recruitment at sites outside of the United States, but it will not reopen recruitment at sites in Eastern Europe. Tricida intends to ensure that no single site in the VALOR-CKD trial provides  $\geq 5\%$  of the total number of trial subjects. FDA's acceptance of the VALOR-CKD data in support of an NDA resubmission, including the acceptability of the data from non-US countries or regions which will comprise a substantial proportion of the data from the trial, will ultimately be a review issue.

### **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. Tricida is currently conducting a renal outcomes clinical trial, VALOR-CKD, to determine if veverimer slows CKD progression in patients with metabolic acidosis associated 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](http://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 trial, VALOR-CKD, and its 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, whether the FDA will accept the Company's resubmission of an NDA for veverimer; 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; 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 (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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