

**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): May 6, 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 May 6, 2021, Tricida, Inc. (the "Company"), issued a press release announcing its financial results for its first quarter ended March 31, 2021. 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 April 27, 2021, the Company announced that it will host a conference call and webcast at 4:30 pm Eastern Time, on May 6, 2021, during which the Company will discuss its financial results for the first quarter ended March 31, 2021 and report its business progress.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, Tricida Announces First Quarter 2021 Financial Results
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: May 6, 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 First Quarter 2021 Financial Results**

Webcast Today at 4:30 pm Eastern Time

SOUTH SAN FRANCISCO, Calif., May 6, 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 and slow CKD progression in patients with chronic kidney disease (CKD), announced today financial results for the three months ended March 31, 2021 and provided an update on key initiatives.

Recent Events

- Tricida continues to execute on recruitment and conduct of the VALOR-CKD renal outcomes trial. As of May 4, 2021, the VALOR-CKD renal outcomes trial has randomized 1,440 of 1,600 subjects with an average treatment duration of approximately 15 months and has accrued 95 of the 511 required subjects with a positively adjudicated primary endpoint event, defined as the time to first occurrence of renal death, end-stage renal disease (ESRD) or a confirmed greater than or equal to 40% reduction in eGFR (DD40).
- Tricida sponsored several presentations at the National Kidney Foundation Spring Clinical Meeting 2021 that occurred April 6 to 10, 2021, including analyses of: 1) the association between metabolic acidosis and accelerated kidney decline, 2) the association in kidney transplant recipients between metabolic acidosis and graft failure and 3) the association in kidney transplant recipients between metabolic acidosis and a higher risk of death. In addition, Tricida presented in vitro data showing that veverimer does not bind to, or affect the ion binding properties of, other non-absorbed binder drugs that are prescribed to patients with CKD, such as RENVELA, VELTASSA, LOKELMA and KAYEXALATE.
- Tricida previously announced that it 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 intends to continue execution of the ongoing VALOR-CKD renal outcomes trial and believes that the optimal path forward for the potential approval of veverimer is to provide additional data to the FDA from the VALOR-CKD renal outcomes trial.

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 patients with DD40 events are expected to have accrued. If the independent unblinded Interim Analysis Committee does not recommend stopping the trial early for efficacy, Tricida 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 patients with DD40 events are expected to have accrued. If the independent unblinded Interim Analysis Committee does not recommend stopping the trial early for efficacy, Tricida will receive no information from this interim analysis.

“Our VALOR-CKD trial is our key focus this year,” said Gerrit Klaerner, Ph.D., Tricida’s Chief Executive Officer and President. “The timing of accrual of primary endpoint events in the VALOR-CKD trial is an important measure moving forward as it will impact our options for next steps in veverimer’s development given our current financial resources.”

Financial Results for the Three Months Ended March 31, 2021

Research and development expense was \$32.2 million and \$49.4 million for the three months ended March 31, 2021 and 2020, respectively. The decrease in research and development expense for the three months ended March 31, 2021 compared to the prior year was primarily due to decreased activities in connection with our veverimer clinical development program related to manufacturing process optimization and the manufacturing of drug substance and lower personnel costs.

General and administrative expense was \$9.9 million and \$23.5 million for the three months ended March 31, 2021 and 2020, respectively. The decrease in general and administrative expense for the three months ended March 31, 2021 compared to the prior year was primarily due to decreased administrative activities in connection with our veverimer clinical development program, including pre-commercialization, medical affairs and personnel costs.

Net loss was \$53.4 million (non-GAAP net loss of \$38.3 million) and \$74.1 million (non-GAAP net loss of \$63.8 million) for the three months ended March 31, 2021 and 2020, respectively. Net loss per basic and diluted share was \$1.06 and \$1.49 for the three months ended March 31, 2021 and 2020, respectively.

As of March 31, 2021, cash, cash equivalents and investments were \$217.7 million.

Financial Guidance

Tricida believes it has financial resources to fund its planned operations into late 2022. Based on the current rate of primary endpoint events in the VALOR-CKD renal outcomes trial, the first and second interim analyses for early stopping of the trial are expected to occur within the time frame of our existing capital.

Tricida Conference Call Information

Tricida will host its First 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, May 6, 2021

4:30 pm Eastern Time

Webcast: IR.Tricida.com

Dial-In: (877) 377-5478

International: (629) 288-0740

Conference ID: 9047649

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 and slow CKD progression 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.

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 "Financial Guidance" and other statements, including the Company's plans and expectations regarding event accrual rates for the VALOR-CKD renal outcomes trial, its plans for interactions and communications with the FDA, its plans and expectations as to the pathway to approval of veverimer by the FDA, if at all, 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; risks related to the Company's ability to retain its key employees and executives; and risks related to the Company's capital requirements and ability to raise sufficient funds for its 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. 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)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 40,510	\$ 137,857
Short-term investments	177,221	171,670
Prepaid expenses and other current assets	2,989	4,488
Total current assets	<u>220,720</u>	<u>314,015</u>
Long-term investments	—	22,757
Property and equipment, net	1,053	1,112
Operating lease right-of-use assets	13,395	13,801
Total assets	<u>\$ 235,168</u>	<u>\$ 351,685</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,321	\$ 3,508
Current operating lease liabilities	2,341	2,079
Accrued expenses and other current liabilities	32,543	28,671
Total current liabilities	<u>40,205</u>	<u>34,258</u>
Term Loan, net	—	76,638
Convertible Senior Notes, net	120,775	118,670
Non-current operating lease liabilities	12,627	13,046
Other long-term liabilities	—	202
Total liabilities	<u>173,607</u>	<u>242,814</u>
Stockholders' equity:		
Preferred stock	—	—
Common stock	50	50
Additional paid-in capital	748,712	742,555
Accumulated other comprehensive income (loss)	(41)	64
Accumulated deficit	<u>(687,160)</u>	<u>(633,798)</u>
Total stockholders' equity	<u>61,561</u>	<u>108,871</u>
Total liabilities and stockholders' equity	<u>\$ 235,168</u>	<u>\$ 351,685</u>

Tricida, Inc.

Condensed Statements of Operations and Comprehensive Loss
(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 32,175	\$ 49,381
General and administrative	9,895	23,526
Total operating expenses	42,070	72,907
Loss from operations	(42,070)	(72,907)
Other income (expense), net	445	813
Interest expense	(5,613)	(2,020)
Loss on early extinguishment of Term Loan	(6,124)	—
Net loss	(53,362)	(74,114)
Other comprehensive income (loss):		
Net unrealized gain (loss) on available-for-sale investments, net of tax	(105)	(232)
Total comprehensive loss	\$ (53,467)	\$ (74,346)
Net loss per share, basic and diluted	\$ (1.06)	\$ (1.49)
Weighted-average number of shares outstanding, basic and diluted	50,247,698	49,841,407

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 March 31,	
	2021	2020
GAAP net loss, as reported	\$ (53,362)	\$ (74,114)
Adjustments:		
Non-cash operating lease costs	248	320
Accretion of Term Loan and Convertible Senior Notes	2,628	751
Loss on early extinguishment of Term Loan	6,124	—
Stock-based compensation	6,042	8,374
Changes in fair value of compound derivative liability	(202)	846
Restructuring costs	220	—
Total adjustments	15,060	10,291
Non-GAAP net loss	\$ (38,302)	\$ (63,823)

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) loss on early extinguishment of Term Loan, (4) stock-based compensation, (5) changes in fair value of compound derivative liability, and (6) 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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