

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): November 5, 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

- 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))

provisions:

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 November 8, 2021, Tricida, Inc. (the "Company"), issued a press release announcing its financial results for its third quarter ended September 30, 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 November 2, 2021, the Company announced that it will host a conference call and webcast at 4:30 pm Eastern Time, on November 8, 2021, during which the Company will discuss its financial results for the third quarter ended September 30, 2021 and report its business progress.

The information contained in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, is furnished pursuant to Item 2.02 of Form 8-K and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly stated by specific reference in such filing.

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

On November 8, 2021, the Company announced that Wilhelm Stahl, Ph.D., the Company's Executive Vice President, Chief Technology Officer, will transition to a part-time employment arrangement and will relinquish his day-to-day responsibilities overseeing the Company's technical operations and supply chain functions, effective January 1, 2022. Dr. Stahl's cash compensation will be reduced on a pro-rata basis, based on the number of hours that he will work, he will continue to vest in his outstanding equity awards in accordance with their terms and he will remain eligible for benefits under our previously disclosed Executive Severance Plan. Following the transition, Dr. Stahl will cease to serve as an executive officer of the Company.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

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



FOR IMMEDIATE RELEASE

Tricida Announces Third Quarter 2021 Financial Results

Webcast Today at 4:30 pm Eastern Time

SOUTH SAN FRANCISCO, Calif., November 8, 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 slow chronic kidney disease (CKD) progression in patients with metabolic acidosis and CKD, announced today financial results for the three and nine months ended September 30, 2021 and provided an update on key initiatives.

Update on Key Initiatives:

- Tricida continued to execute on recruitment and conduct of the VALOR-CKD renal outcomes clinical trial. As of November 5, 2021, the trial has randomized over 1,470 of its planned 1,600 subjects with an average treatment duration of approximately 19 months. The trial has accrued 159 of the 511 required subjects with positively adjudicated primary endpoint events, defined as renal death, end-stage renal disease (ESRD), and/or greater than or equal to 40% reduction in estimated glomerular filtration rate (eGFR).
- There is a substantial likelihood that Tricida will not have adequate resources or be able to obtain such resources on reasonable terms in the necessary timeframe to continue the VALOR-CKD trial to reach the current target of 511 subjects with positively adjudicated primary endpoint events, which we anticipate would not be reached until 2024. As such, Tricida has considered various options to terminate the VALOR-CKD trial early. Tricida requested and was granted a Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss approaches to stopping the VALOR-CKD trial early based on financial resources and the procedures for study close-out. Consistent with feedback provided by the FDA in its preliminary comments for the Type A meeting, Tricida believes that, among the alternatives considered, stopping the VALOR-CKD trial early for administrative reasons pursuant to the existing protocol is likely to provide the most complete and interpretable data, reduce the risk of missing data required for key efficacy analyses, and maintain the integrity of the trial. While the exact timing of the administrative stop will be determined by the company's financial runway, Tricida anticipates that an administrative stop would occur in the first half of 2022. Its goal is to have approximately six months of financial runway upon receipt of the VALOR-CKD data. Also, based on feedback from the FDA, Tricida will halt enrollment of

additional patients in the VALOR-CKD trial in order to focus resources on maximizing the duration of follow-up in subjects who are currently enrolled in the trial.

“Reengaging with the FDA on the topic of how to best stop the VALOR-CKD trial early yielded clear and helpful feedback to ensure interpretability of the resulting data. Even with an early termination, we believe we can address the most important trial objectives,” said Gerrit Klaerner, Ph.D., Tricida’s Chief Executive Officer and President.

Financial Results for the Three and Nine Months Ended September 30, 2021

Research and development expense was \$26.6 million and \$43.0 million for the three months ended September 30, 2021 and 2020, respectively. The decrease in research and development expense for the three months ended September 30, 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. Research and development expense was \$78.6 million and \$121.1 million for the nine months ended September 30, 2021 and 2020, respectively. The decrease in research and development expense for the nine months ended September 30, 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 \$9.1 million and \$29.3 million for the three months ended September 30, 2021 and 2020, respectively. The decrease in general and administrative expense for the three months ended September 30, 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. General and administrative expense was \$28.5 million and \$81.2 million for the nine months ended September 30, 2021 and 2020, respectively. The decrease in general and administrative expense for the nine months ended September 30, 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 \$39.7 million (non-GAAP net loss of \$30.7 million) and \$77.7 million (non-GAAP net loss of \$64.3 million) for the three months ended September 30, 2021 and 2020, respectively, and \$126.6 million (non-GAAP net loss of \$93.6 million) and \$209.9 million (non-GAAP net loss of \$177.0 million) for the nine months ended September 30, 2021 and 2020, respectively. Net loss per basic and diluted share was \$0.79 and \$1.55 for the three months ended September 30, 2021 and 2020, respectively, and \$2.52 and \$4.20 for the nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021, cash, cash equivalents and investments were \$146.8 million.

Financial Guidance

Tricida believes it has financial resources to fund its planned operations through 2022.

Tricida Conference Call Information

Tricida will host its Third 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

Monday, November 8, 2021

4:30 pm Eastern Time

Webcast:	IR.Tricida.com
Dial-in:	(877) 377-5478
International:	(629) 228-0740
Conference ID:	8785726

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, a non-absorbed, orally-administered polymer designed to slow CKD progression in patients with metabolic acidosis and 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. Metabolic acidosis is a condition commonly caused by CKD that is believed to accelerate the progression of kidney deterioration. There are currently no therapies approved by the FDA to slow progression of kidney disease by correcting chronic metabolic acidosis in patients with CKD. 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 "Update on Key Initiatives" and other statements, including the Company's plans and expectations with regard to its interactions and communications with the FDA, its plans and expectations for the VALOR-CKD trial, including early termination of the trial, its plans and expectations as to the pathway to approval of

veverimer by the FDA 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 Company's plans and expectations with regard to its interactions with the FDA, including the potential 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 for its VALOR-CKD trial and 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; 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.

(Financial Tables to Follow)

Tricida, Inc.

Condensed Balance Sheets
(Unaudited)
(In thousands)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,988	\$ 137,857
Short-term investments	129,782	171,670
Prepaid expenses and other current assets	4,404	4,488
Total current assets	<u>151,174</u>	<u>314,015</u>
Long-term investments	—	22,757
Property and equipment, net	836	1,112
Operating lease right-of-use assets	12,576	13,801
Total assets	<u>\$ 164,586</u>	<u>\$ 351,685</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,261	\$ 3,508
Current operating lease liabilities	2,716	2,079
Accrued expenses and other current liabilities	19,754	28,671
Total current liabilities	<u>25,731</u>	<u>34,258</u>
Term Loan, net	—	76,638
Convertible Senior Notes, net	125,194	118,670
Non-current operating lease liabilities	11,759	13,046
Other long-term liabilities	—	202
Total liabilities	<u>162,684</u>	<u>242,814</u>
Stockholders' equity:		
Preferred stock	—	—
Common stock	50	50
Additional paid-in capital	762,317	742,555
Accumulated other comprehensive income (loss)	(77)	64
Accumulated deficit	(760,388)	(633,798)
Total stockholders' equity	<u>1,902</u>	<u>108,871</u>
Total liabilities and stockholders' equity	<u>\$ 164,586</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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 26,635	\$ 42,996	\$ 78,591	\$ 121,134
General and administrative	9,052	29,273	28,497	81,217
Total operating expenses	<u>35,687</u>	<u>72,269</u>	<u>107,088</u>	<u>202,351</u>
Loss from operations	(35,687)	(72,269)	(107,088)	(202,351)
Other income (expense), net	6	907	155	4,395
Interest expense	(3,994)	(6,267)	(13,533)	(12,043)
Loss on early extinguishment of Term Loan	—	—	(6,124)	—
Loss before income taxes	<u>(39,675)</u>	<u>(77,629)</u>	<u>(126,590)</u>	<u>(209,999)</u>
Income tax benefit (expense)	—	(36)	—	50
Net loss	<u>(39,675)</u>	<u>(77,665)</u>	<u>(126,590)</u>	<u>(209,949)</u>
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale investments, net of tax	(15)	(431)	(141)	239
Total comprehensive loss	<u>\$ (39,690)</u>	<u>\$ (78,096)</u>	<u>\$ (126,731)</u>	<u>\$ (209,710)</u>
Net loss per share, basic and diluted	<u>\$ (0.79)</u>	<u>\$ (1.55)</u>	<u>\$ (2.52)</u>	<u>\$ (4.20)</u>
Weighted-average number of shares outstanding, basic and diluted	<u>50,434,879</u>	<u>50,120,086</u>	<u>50,326,474</u>	<u>49,974,388</u>

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
GAAP net loss, as reported	\$ (39,675)	\$ (77,665)	\$ (126,590)	\$ (209,949)
Adjustments:				
Non-cash operating lease costs	78	207	574	597
Accretion of Term Loan and Convertible Senior Notes	2,243	2,915	7,047	5,246
Loss on early extinguishment of Term Loan	—	—	6,124	—
Stock-based compensation	6,649	7,655	19,300	25,108
Changes in fair value of compound derivative liability	—	(49)	(202)	(699)
Restructuring costs	—	2,660	107	2,660
Total adjustments	8,970	13,388	32,950	32,912
Non-GAAP net loss	\$ (30,705)	\$ (64,277)	\$ (93,640)	\$ (177,037)

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, 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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