

**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): **March 29, 2022**



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 March 29, 2022, Tricida, Inc. (the "Company"), issued a press release announcing its financial results for its fourth quarter and full year ended December 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 March 16, 2022, the Company announced that it will host a conference call and webcast at 4:30 pm Eastern Time, on March 29, 2022, during which the Company will discuss its financial results for the fourth quarter and full year ended December 31, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

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



FOR IMMEDIATE RELEASE

Tricida Announces Fourth Quarter and Full Year 2021 Financial Results

Webcast Today at 4:30 pm Eastern Time

SOUTH SAN FRANCISCO, Calif., March 29, 2022 — Tricida, Inc. (Nasdaq: TCDA) announced today financial results for the three months and year ended December 31, 2021 and provided an update on key initiatives.

Business Update

- Tricida continued to execute on the conduct of the VALOR-CKD renal outcomes clinical trial. Enrollment of patients in the VALOR-CKD trial was completed at the end of 2021 with 1,480 subjects randomized. As of March 28, 2022, randomized subjects had an average treatment duration of approximately 24 months, and the trial had accrued 217 subjects with positively adjudicated primary endpoint events, defined as renal death, end-stage renal disease (ESRD), or greater than or equal to 40% reduction in estimated glomerular filtration rate (eGFR).

Upcoming Milestone

- Tricida previously reported that based on its financial runway it intends to stop the VALOR-CKD trial early for administrative reasons in the second quarter of 2022, with continued accrual of primary endpoint events into the third quarter of 2022. The reporting of top-line results from the VALOR-CKD trial is anticipated to occur early in the fourth quarter of 2022, which would allow for approximately six months of financial runway following the announcement.

“Against the backdrop of a pandemic and a war, we have managed to remain on track with our projections for primary endpoint events in the VALOR-CKD trial,” said Gerrit Klaerner, Ph.D., Tricida’s Chief Executive Officer and President. “We are very encouraged by our progress and continue to believe that the VALOR-CKD trial will provide interpretable data to evaluate how treatment with veverimer impacts slowing of CKD progression in patients with metabolic acidosis and CKD.”

Financial Results for the Three Months and Year Ended December 31, 2021

Research and development expense was \$36.8 million and \$27.3 million for the three months ended December 31, 2021 and 2020, respectively, and \$115.4 million and \$148.4 million for the years ended December 31, 2021 and 2020, respectively. The increase in research and development expense for the three months ended December 31, 2021 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. The decrease in research and development expense for the year ended December 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 \$9.1 million and \$21.8 million for the three months ended December 31, 2021 and 2020, respectively, and \$37.6 million and \$103.0 million for the years ended December 31, 2021 and 2020, respectively. The decrease in general and administrative expense for the three months ended December 31, 2021 compared to the prior year was primarily due to restructuring costs, including one-time termination severance payments and contract termination costs, incurred in the prior year and decreased administrative activities in connection with our veverimer clinical development program, including pre-commercialization and medical affairs. The decrease in general and administrative expense for the year ended December 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 and restructuring costs, including one-time termination severance payments and contract termination costs, incurred in the prior year.

Net loss was \$50.0 million (non-GAAP net loss of \$41.1 million) and \$54.8 million (non-GAAP net loss of \$37.4 million) for the three months ended December 31, 2021 and 2020, respectively, and \$176.6 million (non-GAAP net loss of \$134.7 million) and \$264.8 million (non-GAAP net loss of \$214.4 million) for the years ended December 31, 2021 and 2020, respectively. Net loss per basic and diluted share was \$0.92 and \$1.09 for the three months ended December 31, 2021 and 2020, respectively, and \$3.44 and \$5.29 for the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, cash, cash equivalents and investments were \$150.6 million.

Financial Guidance

Tricida currently has the financial resources to fund its planned operations into early in the second quarter of 2023, which is anticipated to be approximately six months from the announcement of its top-line results for the VALOR-CKD trial.

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 Fourth Quarter Financial Results Conference Call

Tuesday, March 29, 2022

4:30 pm Eastern Time

Webcast:	IR.Tricida.com
Dial-in:	(877) 377-5478
International:	(629) 228-0740
Conference ID:	1932119

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. It is estimated to pose a health risk to approximately 4.3 million patients with CKD in the United States. There are currently no therapies approved by the FDA to slow progression of kidney disease by correcting chronic metabolic acidosis in patients with CKD.

For more information about Tricida, please visit [Tricida.com](https://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. These forward-looking statements include, but are not limited to, all of the statements under the heading "Upcoming Milestone" and other statements, including the Company's plans and expectations for the VALOR-CKD trial, including early termination of the trial, event accrual rates for the trial and the estimated timing for receipt of top-line data, and its expectations regarding financial runway. Forward-looking statements 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 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; risks associated with the ongoing conflict in Ukraine; 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)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,113	\$ 137,857
Short-term investments	119,419	171,670
Prepaid expenses and other current assets	5,004	4,488
Total current assets	<u>145,536</u>	<u>314,015</u>
Long-term investments	10,043	22,757
Property and equipment, net	769	1,112
Operating lease right-of-use assets	12,158	13,801
Total assets	<u>\$ 168,506</u>	<u>\$ 351,685</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 10,023	\$ 3,508
Current operating lease liabilities	2,736	2,079
Accrued expenses and other current liabilities	16,721	28,671
Total current liabilities	<u>29,480</u>	<u>34,258</u>
Term Loan, net	—	76,638
Convertible Senior Notes, net	127,512	118,670
Non-current operating lease liabilities	11,296	13,046
Other long-term liabilities	—	202
Total liabilities	<u>168,288</u>	<u>242,814</u>
Stockholders' equity:		
Preferred stock	—	—
Common stock	55	50
Additional paid-in capital	810,618	742,555
Accumulated other comprehensive income (loss)	(91)	64
Accumulated deficit	(810,364)	(633,798)
Total stockholders' equity	<u>218</u>	<u>108,871</u>
Total liabilities and stockholders' equity	<u>\$ 168,506</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 December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 36,773	\$ 27,283	\$ 115,364	\$ 148,417
General and administrative	9,093	21,766	37,590	102,983
Total operating expenses	45,866	49,049	152,954	251,400
Loss from operations	(45,866)	(49,049)	(152,954)	(251,400)
Other income (expense), net	(41)	621	114	5,016
Interest expense	(4,069)	(6,364)	(17,602)	(18,407)
Loss on early extinguishment of Term Loan	—	—	(6,124)	—
Loss before income taxes	(49,976)	(54,792)	(176,566)	(264,791)
Income tax benefit (expense)	—	(50)	—	—
Net loss	(49,976)	(54,842)	(176,566)	(264,791)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale investments, net of tax	(14)	(368)	(155)	(129)
Total comprehensive loss	\$ (49,990)	\$ (55,210)	\$ (176,721)	\$ (264,920)
Net loss per share, basic and diluted	\$ (0.92)	\$ (1.09)	\$ (3.44)	\$ (5.29)
Weighted-average number of shares outstanding, basic and diluted	54,112,250	50,186,615	51,280,697	50,027,735

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,	
	2021	2020	2021	2020
GAAP net loss, as reported	\$ (49,976)	\$ (54,842)	\$ (176,566)	\$ (264,791)
Adjustments:				
Non-cash operating lease costs	(24)	248	550	845
Accretion of Term Loan and Convertible Senior Notes	2,318	3,012	9,365	8,258
Loss on early extinguishment of Term Loan	—	—	6,124	—
Stock-based compensation	6,582	3,190	25,882	28,298
Changes in compound derivative liability	—	(76)	(202)	(775)
Restructuring costs	(1)	11,089	106	13,749
Total adjustments	8,875	17,463	41,825	50,375
Non-GAAP net loss	\$ (41,101)	\$ (37,379)	\$ (134,741)	\$ (214,416)

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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