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): August 5, 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 2.02 Results of Operations and Financial Condition.

On August 5, 2020, Tricida, Inc. (the "Company"), issued a press release announcing its financial results for its second quarter ended June 30, 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 July 29, 2020, the Company announced that it will host a conference call and webcast at 4:30 pm Eastern Time, on August 5, 2020, during which the Company will discuss its financial results for the second quarter ended June 30, 2020 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
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: August 5, 2020

TRICIDA, INC.

By: /s/ Geoffrey M. Parker

Name: Geoffrey M. Parker

Title: Chief Financial Officer and Executive Vice President

Exhibit 99.1

FOR IMMEDIATE RELEASE

Tricida Announces Second Quarter 2020 Financial Results

Webcast Today at 4:30 pm Eastern Time

SOUTH SAN FRANCISCO, Calif., August 5, 2020 (Business Wire) — Tricida, Inc. (Nasdaq: TCDA), a pharmaceutical company focused on the development and commercialization of its 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 three and six months ended June 30, 2020 and provided an update on key initiatives.

Recent Events

- On May 22, 2020, Tricida completed an offering of $200.0 million of its 3.50% Convertible Senior Notes due 2027. Net proceeds from the offering were $193.3 million, after deducting underwriting discounts and commissions and other offering costs.

- In early July, Tricida deployed its field force of approximately 40 Specialty Account Managers in key geographic regions to communicate directly with 70% to 80% of the 5,000 highest-prescribing nephrologists in the United States. The Specialty Account Managers have initiated metabolic acidosis disease awareness education, and to date, have conducted nearly 6000 virtual or in-person engagements with nephrologists and their staff, hosted numerous nephrologists' roundtable meetings and arranged peer-to-peer educational events.

- On July 14, 2020, Tricida received a notification from the U.S. Food and Drug Administration (FDA) stating that, as part of its ongoing review of the company's New Drug Application (NDA), the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. The notification does not specify the deficiencies identified by the FDA. The FDA stated that the notification does not reflect a final decision on the information under review. The company plans to work with the FDA to identify and seek to resolve the deficiencies.

Upcoming Events and Projected Milestones

- The FDA assigned a Prescription Drug User Fee Act, or PDUFA, goal date of August 22, 2020 for the potential approval to market veverimer in the United States. Tricida anticipates that it will receive further clarification related to the FDA notification of July 14, 2020 on or before the PDUFA goal date of August 22, 2020. While the company has no additional information from the FDA since the July 14, 2020 notification, at this time, the company believes it is unlikely to receive approval to market veverimer in the United States on the PDUFA goal date.

- Tricida plans to complete enrollment of patients in its VALOR-CKD confirmatory postmarketing trial in first half of 2021. The VALOR-CKD trial is an outcomes trial comparing veverimer versus placebo in time to renal disease progression in patients with metabolic acidosis and chronic kidney disease (CKD).

“While we won’t speculate what the FDA notification may entail, we are preparing for all eventualities to swiftly resolve any potential issues. However, we remain confident in the fundamentals of veverimer and its underlying value proposition,” said Gerrit Klaerner, Ph.D., Tricida’s Chief Executive Officer and President. “I am reassured by the feedback that we have received from our Specialty Account Managers from their initial interactions with community nephrologists that confirms the unmet need to treat metabolic acidosis.”

Financial Results for the Three and Six Months Ended June 30, 2020

Research and development expense was $28.8 million and $29.0 million for the three months ended June 30, 2020 and 2019, respectively, and $78.1 million and $60.4 million for the six months ended June 30, 2020 and 2019, respectively. The decrease in research and development expense for the three months ended June 30, 2020 compared to the prior year was primarily due to decreased activities in connection with our veverimer clinical development program related to reduced expenditures in our clinical trials, partially offset by an increase in manufacturing process optimization and increased personnel costs. The increase in research and development expense for the six months ended June 30, 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, as well as increased personnel costs.

General and administrative expense was $28.4 million and $8.9 million for the three months ended June 30, 2020 and 2019, respectively, and $51.9 million and $15.2 million for the six months ended June 30, 2020 and 2019, respectively. The increases in general and administrative expense in the three and six months ended June 30, 2020 compared to the three and six months ended June 30, 2019 were primarily due to increased administrative costs supporting the increased activities in connection with our veverimer clinical development program, including pre-commercialization, Medical Affairs, professional service costs, and increased personnel costs.

Net loss was $58.2 million (non-GAAP net loss of $48.9 million) and $36.6 million (non-GAAP net loss of $31.5 million) for the three months ended June 30, 2020 and 2019, respectively, and $132.3 million (non-GAAP net loss of $112.8 million) and $74.5 million (non-GAAP net loss of $65.9 million) for the six months ended June 30, 2020 and 2019, respectively. Net loss per basic and diluted share was $1.16 and

$0.75 for the three months ended June 30, 2020 and 2019, respectively, and $2.65 and $1.64 for the six months ended June 30, 2020 and 2019, respectively.

As of June 30, 2020, cash, cash equivalents and investments were $436.9 million.

Today's Conference Call and Webcast

Tricida will host a conference call today at 4:30 pm Eastern Time to discuss its financial results and business progress. Please access the Tricida Conference Call as follows:

Tricida Second Quarter 2020 Conference Call

4:30 pm Eastern Time Today

Webcast:	**IR.Tricida.com**
Dial-in:	**(877) 377-5478**
International:	(629) 228-0740
Conference ID:	**8994536**

A replay of the webcast will be available on the Investor Relations page of 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 drug candidate, veverimer (TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis in patients 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 three million patients with CKD in the United States. Tricida is currently conducting its confirmatory postmarketing trial, VALOR-CKD, of veverimer. The Tricida NDA for veverimer has been accepted for review by the FDA through the Accelerated Approval Program. The FDA has assigned a PDUFA goal date of August 22, 2020.

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 and Section 21E of the Securities Exchange Act of 1934 ("Exchange Act"). 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 Events and Projected Milestones" and other statements, including the potential receipt and timing of the FDA's approval of the NDA, the potential receipt and timing of further clarification related to the FDA notification of July 14, 2020, the potential availability of the Accelerated Approval Program, as well as the approvability of veverimer under that program, the Company's expectations with regard to its interactions

and communications with the FDA, plans and expectations as to the PDUFA date, and statements regarding the therapeutic potential of, and potential clinical and commercial development plans for, veverimer. Forward-looking statements involve known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, among others, that we may not be able to address all of the issues that relate to the deficiencies the FDA may identify with respect to veverimer; that we may not be able to achieve upcoming milestones; the cost, timing and results of clinical trials and other studies; that many drug candidates that have completed Phase 3 trials do not become approved drugs on a timely or cost effective basis, or at all; there can be no assurance that the FDA would approve an NDA through the Accelerated Approval Program, or at all, and even if approval for a drug is obtained, there can be no assurance that it will be adopted in the market or accepted as a benefit to patients and healthcare providers; possible safety and efficacy concerns; and that we completely rely on third-party suppliers and manufacturers for many aspects of our business. These and other factors that may affect our future results of operations are identified and described in more detail in our filings with the Securities and Exchange Commission, including the Company's most recent Annual Report filed on Form 10-K and our subsequently filed Quarterly Reports 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)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 41,900	$ 18,574
Short-term investments	345,632	289,424
Prepaid expenses and other current assets	9,830	4,744
Total current assets	397,362	312,742
Long-term investments	49,371	46,980
Property and equipment, net	1,432	2,728
Operating lease right-of-use assets	8,734	9,376
Total assets	$ 456,899	$ 371,826
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,839	$ 5,911
Current operating lease liabilities	1,088	1,072
Current Term Loan	6,784	—
Accrued expenses and other current liabilities	20,769	32,780
Total current liabilities	34,480	39,763
Non-current Term Loan, net	67,952	58,374
Convertible Senior Notes, net	114,645	—
Non-current operating lease liabilities	8,515	8,783
Other long-term liabilities	327	1,023
Total liabilities	225,919	107,943
Stockholders' equity:		
Preferred stock	—	—
Common stock	50	50
Additional paid-in capital	731,358	632,647
Accumulated other comprehensive income (loss)	863	193
Accumulated deficit	(501,291)	(369,007)
Total stockholders' equity	230,980	263,883
Total liabilities and stockholders' equity	$ 456,899	$ 371,826

Tricida, Inc.

Condensed Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 28,757	$ 28,976	$ 78,138	$ 60,399
General and administrative	28,418	8,861	51,944	15,213
Total operating expenses	57,175	37,837	130,082	75,612
Loss from operations	(57,175)	(37,837)	(130,082)	(75,612)
Other income (expense), net	2,675	2,602	3,488	3,869
Interest expense	(3,756)	(1,391)	(5,776)	(2,780)
Loss before income taxes	(58,256)	(36,626)	(132,370)	(74,523)
Income tax benefit	86	—	86	—
Net loss	(58,170)	(36,626)	(132,284)	(74,523)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale investments, net of tax	902	480	670	782
Total comprehensive loss	$ (57,268)	$ (36,146)	$ (131,614)	$ (73,741)
Net loss per share, basic and diluted	$ (1.16)	$ (0.75)	$ (2.65)	$ (1.64)
Weighted-average number of shares outstanding, basic and diluted	49,960,072	48,674,238	49,900,739	45,489,861

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
GAAP net loss, as reported	$ (58,170)	$ (36,626)	$ (132,284)	$ (74,523)
Adjustments:				
Non-cash operating lease costs	70	209	390	413
Stock-based compensation	9,079	4,413	17,453	7,071
Accretion of Term Loan and Convertible Senior Notes	1,580	523	2,331	1,011
Changes in fair value of compound derivative liability	(1,496)	(9)	(650)	165
Total adjustments	9,233	5,136	19,524	8,660
Non-GAAP net loss	$ (48,937)	$ (31,490)	$ (112,760)	$ (65,863)

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) stock-based compensation, (3) accretion of Term Loan and Convertible Senior Notes and (4) changes in fair value of compound derivative liability, 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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