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 8, 2019

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)

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

☒ 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 8, 2019, Tricida, Inc. (the "Company"), issued a press release announcing its financial results for its second quarter ended June 30, 2019. A copy of this earnings release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. On August 1, 2019, the Company announced that it will host a conference call and webcast at 4:30 pm Eastern Time, on August 8, 2019, during which the Company will discuss its financial results for the second quarter ended June 30, 2019 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 No.	Description
99.1	Press Release

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.

TRICIDA, INC.

Dated: August 8, 2019

By: /s/ Geoffrey M. Parker
Name: Geoffrey M. Parker
Title: Chief Financial Officer and Senior Vice President

Exhibit 99.1

Tricida Announces Second Quarter 2019 Financial Results

Narrows Timing of Planned NDA Submission to the Third Quarter of 2019

Back-to-Back Publications in 'The Lancet' Highlight Positive Clinical Trial Results of Veverimer

Webcast Today at 4:30 pm Eastern Time

SOUTH SAN FRANCISCO, Calif., August 8, 2019 (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, 2019 and provided an update on key initiatives, including its planned submission of the New Drug Application (NDA) for veverimer.

Tricida has narrowed the timing for its planned NDA submission under the Accelerated Approval Program from the second half of 2019 to the third quarter of 2019 based on Tricida's recent pre-NDA meeting with the U.S. Food and Drug Administration (FDA), which included discussion of the positive TRCA-301E trial results. Tricida has made significant progress in the enrollment of its confirmatory postmarketing trial and, while the trial is not yet fully enrolled, the overall status and rate of enrollment were deemed sufficient by the FDA for Tricida to plan for the NDA submission for veverimer in the third quarter of 2019. Tricida intends to provide an update by the end of the year on its estimate for enrolling the last patient in its postmarketing trial.

Recent Highlights

- *The Lancet* published positive long-term Phase 3 clinical trial results of veverimer (TRC101) in June 2019. This publication followed the earlier publication in *The Lancet* of 12-week, Phase 3 clinical trial results in March 2019.
- Positive pre-NDA meeting with the FDA.
- Received NDA-enabling 12-month registration stability data for veverimer.

Upcoming Events and Projected Milestones

- Planned submission of the NDA for veverimer through the FDA's Accelerated Approval Program in the third quarter of 2019.
- Tricida will host its first Investor Day, planned for October 15, 2019, to highlight its pre-launch activities and commercial strategy for veverimer.

- Tricida will have a major presence at the American Society of Nephrology (ASN) Kidney Week Meeting in Washington, DC, November 5-10, 2019.

“Our planned NDA submission for veverimer this quarter will be a major achievement and I am proud of the Tricida team for taking the program from Investigational New Drug application to our planned NDA submission in less than four years,” said Gerrit Klaerner, Ph.D., Tricida’s chief executive officer and president. “With the combination of our experienced team and strong clinical data that was presented in our second Lancet publication, we look forward to the potential approval and launch of veverimer next year.”

Financial Results for the Quarter Ended June 30, 2019

Research and development expense was $29.0 million and $21.0 million for the three months ended June 30, 2019 and 2018, respectively, and $60.4 million and $37.7 million for the six months ended June 30, 2019 and 2018, respectively. The increases in research and development expense in the three and six months ended June 30, 2019 compared to the prior year was primarily due to increased activities in connection with our veverimer clinical development program, including increased drug substance manufacturing, as well as increased personnel and related costs.

General and administrative expense was $8.9 million and $4.2 million for the three months ended June 30, 2019 and 2018, respectively, and $15.2 million and $7.7 million for the six months ended June 30, 2019 and 2018, respectively. The increases in general and administrative expense in the three and six months ended June 30, 2019 compared to the prior year was primarily due to increased administrative costs supporting the increased activities in connection with our veverimer clinical development program, increased headcount and higher professional service fees.

Net loss was $36.6 million (non-GAAP net loss of $31.7 million) and $25.4 million (non-GAAP net loss of $24.4 million) for the three months ended June 30, 2019 and 2018, respectively, and $74.5 million (non-GAAP net loss of $66.3 million) and $45.9 million (non-GAAP net loss of $44.3 million) for the six months ended June 30, 2019 and 2018, respectively. Net loss per basic and diluted share was $0.75 and $10.89 for the three months ended June 30, 2019 and 2018, respectively, and $1.64 and $19.91 for the six months ended June 30, 2019 and 2018, respectively.

As of June 30, 2019, cash, cash equivalents and investments were $405.3 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 2019 Conference Call

4:30 pm Eastern Time Today

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

Conference ID: 5066987

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 chronic kidney disease (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 has successfully completed all of the clinical trials that it planned to complete prior to submission of an NDA to the U.S. Food and Drug Administration (FDA). Tricida plans to submit an NDA in the third quarter of 2019, seeking approval of veverimer through the FDA's Accelerated Approval Program.

For more information about Tricida, please visit www.Tricida.com.

Cautionary Note on Forward-Looking Statements

This press release includes forward-looking statements, including for example, all of the statements under the heading "Upcoming Events and Projected Milestones" and other statements about our ability and timing to submit an NDA or the potential approval and launch of veverimer under the FDA's Accelerated Approval Program. 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 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 under 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 to manufacture our clinical drug supply. The forward-looking statements contained in this press release reflect Tricida's current views with respect to future events, and Tricida does not undertake and specifically disclaims any obligation to update any forward-looking statements.

(Financial Tables to Follow)

Tricida, Inc.

Condensed Balance Sheets
(Unaudited)
(In thousands)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 24,797	$ 37,172
Short-term investments	369,037	203,906
Prepaid expenses and other current assets	4,666	3,269
Total current assets	398,500	244,347
Long-term investments	11,497	2,287
Property and equipment, net	1,892	1,215
Operating lease right-of-use assets	1,843	—
Total assets	$ 413,732	$ 247,849
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,673	$ 8,460
Current operating lease liabilities	1,046	—
Accrued expenses and other current liabilities	22,296	6,344
Total current liabilities	28,015	14,804
Term Loan	37,463	38,071
Non-current operating lease liabilities	994	—
Other long-term liabilities	416	449
Total liabilities	66,888	53,324
Stockholders' equity:		
Preferred stock	—	—
Common stock	49	42
Additional paid-in capital	612,883	386,830
Accumulated other comprehensive income (loss)	629	(153)
Accumulated deficit	(266,717)	(192,194)
Total stockholders' equity	346,844	194,525
Total liabilities and stockholders' equity	$ 413,732	$ 247,849

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,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 28,976	$ 21,034	$ 60,399	$ 37,667
General and administrative	8,861	4,245	15,213	7,710
Total operating expenses	37,837	25,279	75,612	45,377
Loss from operations	(37,837)	(25,279)	(75,612)	(45,377)
Other income (expense), net	2,602	827	3,869	740
Interest expense	(1,391)	(910)	(2,780)	(1,229)
Net loss	(36,626)	(25,362)	(74,523)	(45,866)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale investments	480	41	782	(13)
Total comprehensive loss	$ (36,146)	$ (25,321)	$ (73,741)	$ (45,879)
Net loss per share, basic and diluted	$ (0.75)	$ (10.89)	$ (1.64)	$ (19.91)
Weighted-average number of shares outstanding, basic and diluted	48,674,238	2,329,085	45,489,861	2,304,087

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,	
	2019	2018	2019	2018
GAAP net loss, as reported	$ (36,626)	$ (25,362)	$ (74,523)	$ (45,866)
Adjustments:				
Non-cash stock-based compensation expense	4,413	970	7,071	1,323
Non-cash Term Loan discount and issuance costs	523	376	1,011	504
Changes in fair value of compound derivative liabilities and warrants	(9)	(372)	165	(236)
Total adjustments	4,927	974	8,247	1,591
Non-GAAP net loss	$ (31,699)	$ (24,388)	$ (66,276)	$ (44,275)

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 represent GAAP net loss adjusted to exclude (1) stock-based compensation expense, (2) non-cash interest expense related to Tricida's Term Loan discount and issuance costs and (3) changes in fair value of compound derivative liabilities and warrants within our reconciliation 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:
Jackie Cossmon, IRC
Tricida, Inc.
Vice President of Investor Relations and Communications
IR@Tricida.com