

**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 8, 2018

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 No.)

7000 Shoreline Court
Suite 201
South San Francisco, CA 94080
(Address of principal executive offices)

Registrant's telephone number, including area code: (415) 429-7800

Not Applicable
(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 (§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.

TRICIDA

Tricida Announces Third Quarter 2018 Financial Results

Advanced Key Initiatives for NDA Submission

Launched Non-Branded Metabolic Acidosis Disease Awareness Campaign

Presented TRCA-301 Pivotal Trial Results at ASN Kidney Week Late-Breaker Session

Webcast Today at 5:00 pm ET

SOUTH SAN FRANCISCO, Calif., November 8, 2018 (Business Wire) — Tricida, Inc. (Nasdaq: TCDA), a pharmaceutical company focused on the development and commercialization of TRC101, a non-absorbed, orally-dosed polymer designed as a potential treatment for metabolic acidosis in patients with chronic kidney disease (CKD), announced today financial results for the three and nine months ended September 30, 2018 and provided an update on key initiatives.

“We’ve made significant progress on our major initiatives supporting both our plan to submit our New Drug Application (NDA) under the Accelerated Approval Pathway in the second half of 2019 and our pre-launch activities for TRC101,” said Gerrit Klaerner, Ph.D., Tricida’s chief executive officer and president. “Our pre-launch activities, initiated at the American Society of Nephrology (ASN) Kidney Week 2018 meeting, included a unique, non-branded metabolic acidosis disease awareness campaign. Nephrologists were eager to hear the latest information about metabolic acidosis and its potential impact on CKD progression. We also drew significant attention at the meeting with our new mobile app, branded as Neph⁺, featuring the 8-variable kidney failure risk equation, KDIGO guideline recommendations and a convenient calculator for equations commonly used by nephrologists.”

Recent Highlights

- Initiated patient screening in the VALOR-CKD postmarketing clinical trial at multiple clinical study sites in multiple countries. The VALOR-CKD trial is designed to evaluate TRC101’s ability to slow progression of CKD in patients with CKD and metabolic acidosis.
 - Launched a non-branded disease awareness campaign at the ASN Kidney Week 2018 meeting, introducing a new mobile app, Neph⁺, an educational video and two new nephrology-oriented websites, NephPlus.com and MetabolicAcidosisInsights.com, to provide ready access to the new Neph⁺ app and to expand awareness of the complications of metabolic acidosis in patients with CKD.
 - Presented the results of our successful, pivotal, Phase 3 TRCA-301 clinical trial at the Late-Breaking Clinical Trials Posters session at the ASN Kidney Week 2018 Meeting. The trial met both its primary and secondary endpoints with highly statistically significant results and showed a
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statistically significant difference favoring TRC101 in the pre-specified exploratory endpoint evaluating the effect of TRC101 on self-reported responses to the physical functioning subpart of the Kidney Disease and Quality of Life Short Form survey (KDQOL-SF survey). Additionally, new data showing statistically significant results in favor of TRC101 were presented from a post-hoc rank-based analysis of the second exploratory endpoint, the repeated chair stand test, which is an objective measure of physical function.

Upcoming Events and Projected Milestones

- Completion of the 40-week safety extension trial, TRCA-301E, in the first half of 2019.
- Availability of NDA-enabling 12-month registration stability data for TRC101 in mid-2019.
- Submission of our NDA for TRC101, seeking approval of TRC101 through the FDA's Accelerated Approval Program, in the second half of 2019.

Financial Results for the Quarter Ended September 30, 2018

Research and development expense was \$25.2 million and \$7.7 million for the three months ended September 30, 2018 and 2017, respectively, and \$62.9 million and \$18.1 million for the nine months ended September 30, 2018 and 2017, respectively. The increases in research and development expense in the three- and nine-month periods of 2018 compared to the prior year were primarily due to increased activities in connection with our TRC101 clinical development program, including increased drug substance manufacturing, as well as increased personnel and related costs.

General and administrative expense was \$4.2 million and \$3.1 million for the three months ended September 30, 2018 and 2017, respectively, and \$11.9 million and \$8.3 million for the nine months ended September 30, 2018 and 2017, respectively. The increases in general and administrative expense in the three- and nine-month periods of 2018 compared to the prior year were primarily due to increased administrative costs supporting the increased activities in connection with our TRC101 clinical development program, including increased personnel and related costs and other general and administrative expenses.

Net loss was \$29.1 million (non-GAAP net loss of \$27.0 million) and \$10.8 million (non-GAAP net loss of \$10.6 million) for the three months ended September 30, 2018 and 2017, respectively, and \$75.0 million (non-GAAP net loss of \$71.3 million) and \$20.7 million (non-GAAP net loss of \$25.8 million) for the nine months ended September 30, 2018 and 2017, respectively. Net loss per basic and diluted share was \$0.71 and \$4.81 for the three months ended September 30, 2018 and 2017, respectively, and \$4.86 and \$9.67 for the nine months ended September 30, 2018, and 2017, respectively.

As of September 30, 2018, cash, cash equivalents and short-term investments were \$260.5 million.

Today's Conference Call and Webcast

Tricida will host a conference call today at 5:00 pm Eastern Time to discuss its financial results and business progress. Please access the Tricida Conference Call as follows:

Tricida Third Quarter 2018 Conference Call

5:00 pm Eastern Time Today

Website: IR.Tricida.com
Dial-in: (877) 377-5478
International: (629) 228-0740
Conference ID: 7553409

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 TRC101, a non-absorbed, orally-administered polymer designed as a potential treatment for 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. Tricida has successfully completed a pivotal Phase 3, double-blind, placebo-controlled trial of TRC101 in patients with CKD and metabolic acidosis. The results of this Phase 3 trial, along with results from a successful double-blind, randomized, placebo-controlled Phase 1/2 trial and an ongoing safety extension trial, TRCA-301E, are intended to serve as the basis for the submission of an NDA for TRC101 under 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 to submit an NDA for TRC101 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)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 155,218	\$ 9,774
Short-term investments	105,313	57,740
Prepaid expenses and other current assets	2,088	1,910
Total current assets	<u>262,619</u>	<u>69,424</u>
Property and equipment, net	1,324	1,150
Total assets	<u>\$ 263,943</u>	<u>\$ 70,574</u>
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 6,229	\$ 3,861
Accrued expenses and other current liabilities	14,489	7,361
Total current liabilities	<u>20,718</u>	<u>11,222</u>
Term loan	23,714	—
Other long-term liabilities	440	323
Total liabilities	<u>44,872</u>	<u>11,545</u>
Convertible preferred stock	—	147,070
Stockholders' equity (deficit):		
Common stock	42	2
Additional paid-in capital	383,419	1,356
Accumulated other comprehensive loss	(40)	(13)
Accumulated deficit	(164,350)	(89,386)
Total stockholders' equity (deficit)	<u>219,071</u>	<u>(88,041)</u>
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 263,943</u>	<u>\$ 70,574</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,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 25,230	\$ 7,725	\$ 62,897	\$ 18,136
General and administrative	4,178	3,149	11,888	8,329
Total operating expenses	29,408	10,874	74,785	26,465
Loss from operations	(29,408)	(10,874)	(74,785)	(26,465)
Change in fair value—preferred stock tranche obligation	—	—	—	5,649
Other income (expense), net	1,247	71	1,987	82
Interest expense	(937)	(2)	(2,166)	(6)
Net loss	(29,098)	(10,805)	(74,964)	(20,740)
Other comprehensive loss:				
Net unrealized gain (loss) on available-for-sale securities, net of tax	(14)	8	(27)	(2)
Comprehensive loss	\$ (29,112)	\$ (10,797)	\$ (74,991)	\$ (20,742)
Net loss per share, basic and diluted	\$ (0.71)	\$ (4.81)	\$ (4.86)	\$ (9.67)
Weighted-average number of shares outstanding, basic and diluted	41,261,703	2,244,913	15,415,194	2,144,190

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,	
	2018	2017	2018	2017
GAAP net loss, as reported	\$ (29,098)	\$ (10,805)	\$ (74,964)	\$ (20,740)
Adjustments:				
Non-cash stock-based compensation expense	1,706	219	3,029	596
Non-cash term loan discount and issuance costs	397	—	902	—
Mark-to-market adjustment on financial instruments	(2)	5	(238)	(5,636)
Total adjustments	2,101	224	3,693	(5,040)
Non-GAAP net loss	\$ (26,997)	\$ (10,581)	\$ (71,271)	\$ (25,780)

Use of Non-GAAP Financial Measures

We supplement our consolidated 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 income, 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 income” is not based on any standardized methodology prescribed by GAAP and represent GAAP net income 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) mark-to market adjustments related to financial instruments held (which include preferred stock tranche obligations, warrants and derivatives) within our reconciliation of our GAAP to Non-GAAP net income. 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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