

**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, 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 Announces Second Quarter 2018 Financial Results and Provides Update on Key Initiatives

Completed Positive Pivotal Phase 3 Trial for TRC101

Completed \$255.6 Million Initial Public Offering

Webcast Today at 5:00 pm ET

SOUTH SAN FRANCISCO, Calif., August 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 to treat metabolic acidosis in patients with chronic kidney disease (CKD), announced today financial results for the three and six months ended June 30, 2018 and provided an update on key initiatives.

"Following the positive results of our pivotal Phase 3 trial and the successful completion of our initial public offering in which we raised gross proceeds of \$255.6 million, we are now focused on our plan to file the NDA for TRC101 in the second half of 2019," said Gerrit Klaerner, Ph.D., Tricida's chief executive officer and president. "TRC101 holds the promise of potentially slowing the progression of CKD through the treatment of metabolic acidosis, a condition that affects approximately three million CKD patients in the United States. We are now initiating the VALOR-CKD trial, a large multi-center, placebo-controlled, postmarketing study of TRC101, with the goal of demonstrating that treating metabolic acidosis with TRC101 can lead to the slowing of CKD progression and thereby delay the ultimate need for dialysis or a kidney transplant."

Recent Highlights

- Reported results from the pivotal Phase 3 clinical trial, TRCA-301, which met both its primary and secondary endpoints with high statistical significance in May 2018.
 - Completed enrollment of 196 subjects into the 40-week safety extension trial, TRCA-301E, in May 2018.
 - Completed an initial public offering (IPO) for total gross proceeds of approximately \$255.6 million in July 2018.
 - Submitted the protocol for the VALOR-CKD confirmatory postmarketing clinical trial, also known as TRCA-303 to the U.S. Food and Drug Administration (FDA) in July 2018.
 - Formed the VALOR-CKD Steering Committee that includes world-recognized experts in nephrology in May 2018.
 - Announced the addition of Dawn Parsell, Ph.D., to the executive management team as Senior Vice President of Clinical Development in August 2018.
 - Presented a poster, co-authored with Navdeep Tangri, M.D., Ph.D., FRCP(C), at the National Kidney Foundation (NKF) 2018 Spring Clinical Meetings demonstrating the linear relationship between treating metabolic acidosis and the risk of CKD progression in April 2018.
 - Received confirmation of the TRC101 generic name *verimer* in July 2018.
-

Upcoming Events and Projected Milestones

- Presentation of results from the pivotal Phase 3 clinical trial, TRCA-301, at the American Society of Nephrology (ASN) Kidney Week 2018 Meeting in October 2018.
- Initiation of a non-branded disease education campaign focused on metabolic acidosis and the progression of CKD, including a mobile software app focused on helping nephrologists calculate the risk of CKD progression, at the ASN Kidney Week 2018 Meeting in October 2018.
- Initiation of clinical study sites for the VALOR-CKD trial in the second half of 2018.
- Completion of the 40-week safety extension trial, TRCA-301E, in the first half of 2019.
- Availability of New Drug Application (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 June 30, 2018

Research and development expense was \$21.0 million and \$4.6 million for the three months ended June 30, 2018 and 2017, respectively. The increase in research and development expense was 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. For the six months ended June 30, 2018 and 2017, respectively, research and development expense was \$37.7 million and \$10.4 million. The increase in research and development expense was primarily due to increased activities in connection with our TRC101 clinical development program, resulting in increased clinical development costs and increased personnel and related costs.

General and administrative expense was \$4.2 million and \$2.4 million for the three months ended June 30, 2018 and 2017, respectively. The increase in general and administrative expense was 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. For the six months ended June 30, 2018 and 2017, respectively, general and administrative expense was \$7.7 million and \$5.2 million. The increase in general and administrative expense was primarily due to increased administrative costs supporting the increased activities in connection with our TRC101 clinical development program, including increased personnel and related costs.

Net losses were \$25.4 million (non-GAAP net loss of \$24.4 million) and \$7.7 million (non-GAAP net loss of \$6.7 million) for the three months ended June 30, 2018 and 2017, respectively, and \$45.9 million (non-GAAP net loss of \$44.3 million) and \$9.9 million (non-GAAP net loss of \$15.2 million) for the six months ended June 30, 2018 and 2017, respectively. Net loss per basic and diluted share is based on a weighted-average number of shares outstanding prior to the completion of our IPO on July 2, 2018 and was \$10.89 and \$3.60 for the three months ended June 30, 2018 and 2017, respectively, and \$19.91 and \$4.75 for the six months ended June 30, 2018, and 2017, respectively. The effect of the 13,455,000 shares of common stock issued at the consummation of our IPO along with the conversion of our convertible preferred stock into 26,187,321 shares of common stock, was not considered in the net loss per basic and diluted share calculation at June 30, 2018 since the IPO consummated on July 2, 2018. Applying the number of outstanding shares on July 2, 2018, following the consummation of Tricida's IPO, net loss per basic and diluted share would be \$0.60 and \$1.09 for the three and six months ended June 30, 2018, respectively. This additional information regarding net loss per share is provided to investors to enable analysis of our net loss per share based on the preferred stock conversion and the additional issuance of common shares from the IPO using the if converted method as of the beginning of the first period presented or the original date of issuance, if later.

As of June 30, 2018, cash, cash equivalents and short-term investments were \$55.3 million, which does not include \$237.7 million of proceeds from our IPO, net of underwriting discounts and commissions related to the offering.

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 provide a general business update. Please access the Tricida Conference Call as follows:

Tricida Second 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: 3097326

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 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. Tricida has successfully completed a pivotal Phase 3, double-blind, placebo-controlled trial of TRC101 in CKD patients with 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 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 participate in upcoming events or 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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,788	\$ 9,774
Short-term investments	49,518	57,740
Prepaid expenses and other current assets	1,550	1,910
Total current assets	56,856	69,424
Property and equipment, net	1,303	1,150
Deferred offering costs	6,468	—
Total assets	\$ 64,627	\$ 70,574
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 11,436	\$ 3,861
Accrued expenses and other current liabilities	14,134	7,361
Total current liabilities	25,570	11,222
Term loan	23,317	—
Other long-term liabilities	483	323
Total liabilities	49,370	11,545
Convertible preferred stock	147,528	147,070
Stockholders' deficit:		
Common stock	2	2
Additional paid-in capital	3,005	1,356
Accumulated other comprehensive loss	(26)	(13)
Accumulated deficit	(135,252)	(89,386)
Total stockholders' deficit	(132,271)	(88,041)
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 64,627	\$ 70,574

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,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 21,034	\$ 4,567	\$ 37,667	\$ 10,411
General and administrative	4,245	2,355	7,710	5,180
Total operating expenses	25,279	6,922	45,377	15,591
Loss from operations	(25,279)	(6,922)	(45,377)	(15,591)
Change in fair value—preferred stock tranche obligation	—	(813)	—	5,649
Other income (expense), net	827	11	740	11
Interest expense	(910)	(2)	(1,229)	(4)
Net loss	(25,362)	(7,726)	(45,866)	(9,935)
Other comprehensive loss:				
Net unrealized gain (loss) on marketable securities, net of tax	41	(9)	(13)	(10)
Comprehensive loss	\$ (25,321)	\$ (7,735)	\$ (45,879)	\$ (9,945)
Net loss per share, basic and diluted	\$ (10.89)	\$ (3.60)	\$ (19.91)	\$ (4.75)
Weighted-average number of shares outstanding, basic and diluted	2,329,085	2,145,965	2,304,087	2,092,993
Pro forma net loss per share, basic and diluted *	\$ (0.60)		\$ (1.09)	
Pro forma weighted-average number of shares outstanding, basic and diluted *	41,949,686		41,923,503	

* Pro forma net loss per share, basic and diluted, and pro forma weighted-average number of shares outstanding, basic and diluted, are provided to investors to enable analysis of our net loss per share based on the preferred stock conversion and the additional issuance of common shares from the IPO using the if converted method as of the beginning of the first period presented or the original date of issuance, if later.

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,	
	2018	2017	2018	2017
GAAP net loss, as reported	\$ (25,362)	\$ (7,726)	\$ (45,866)	\$ (9,935)
Adjustments:				
Non-cash stock-based compensation expense	970	186	1,323	376
Non-cash debt offering costs	376	—	504	—
Mark-to-market adjustment on financial instruments	(372)	813	(236)	(5,649)
Total adjustments	974	999	1,591	(5,273)
Non-GAAP net loss	\$ (24,388)	\$ (6,727)	\$ (44,275)	\$ (15,208)

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 offering 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.

Contact:
Jackie Cossmon, IRC
Tricida, Inc.
Vice President of Investor Relations and Communications
IR@Tricida.com

#####