Tricida Announces First Quarter 2020 Financial Results

May 7, 2020

Webcast Today at 4:30 pm Eastern Time

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 7, 2020-- 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 months ended March 31, 2020 and provided an update on key initiatives.

Recent Highlights

- Presented clinical trial data at the National Kidney Foundation Virtual Spring Clinical Meeting on veverimer's mechanism of action that leads to rapid onset of effect and two subgroup analyses of the one-year TRCA-301/TRCA-301E trial that demonstrate safety and efficacy of veverimer in patients with diabetes and with congestive heart failure. Additionally, a poster on CKD as a model of accelerated aging that highlighted the importance of the improvements in physical functioning seen with veverimer in the TRCA-301E trial was presented.
- Sponsored two presentations at the National Kidney Foundation Virtual Spring Clinical Meeting that showed metabolic acidosis is an independent risk factor for all-cause mortality in patients with CKD and that patients with metabolic acidosis and CKD are undertreated and, for those treated, discontinuation rates of oral alkali therapy are high.
- Deployed a field team of 10 Medical Science Liaisons, or MSLs, to engage virtually in scientific exchange with nephrologists.
- Expanded metabolic acidosis disease awareness efforts through significant digital direct targeting to nephrologists and healthcare providers, generating a 95% increase in traffic to the MetabolicAcidosisInsights.com website in the first quarter of 2020 compared to the fourth quarter of 2019 and achieved in the first quarter of 2020 approximately 3 million digital impressions through paid search, display media and targeted emails.
- Engaged with over 85 healthcare payer organizations that represent over 290 million lives to provide disease education in advance of the potential launch of veverimer, if approved. Engagements included presentations of data from the analysis of a large deidentified healthcare database of patients with metabolic acidosis and CKD compared with patients with CKD and normal serum bicarbonate levels. Data show significant differences in risk of progression of 1 or more CKD stages, initiating dialysis, cardiovascular outcomes, fractures, mortality and overall costs to the healthcare system.
- Announced the hiring of Robert McKague as Executive Vice President, General Counsel and Chief Compliance Officer.
- Supported charitable donations from employees by matching their contributions to organizations supporting the effort to help those impacted by the COVID-19 pandemic. Together with Tricida's 100% match, we donated over $100,000 to local, national and international charities. Our N-95 masks and other protective equipment were donated to local hospitals in hopes of protecting health care workers as they care for patients with COVID-19.

Upcoming Events and Projected Milestones

- Hire 40 specialty account managers in the second quarter of 2020 to be deployed in key geographic regions to communicate directly with 70% to 80% of the 5000 highest-prescribing nephrologists in the United States.
- Veverimer PDUFA goal date of August 22, 2020.
- Commercial launch of veverimer anticipated in the second half of 2020, which will include an extensive digital campaign to expand the reach of our promotional efforts for veverimer, if approved.

Tricida also reported today that in the company's late cycle meeting with the FDA, held in May 2020, the FDA indicated it currently does not plan to hold a Cardiovascular and Renal Drugs Advisory Committee meeting to discuss veverimer, due in part to the logistical challenges posed by COVID-19. Tricida continues to work with the FDA on outstanding topics in order to enable initial approval of veverimer through the Accelerated Approval Program.

"COVID-19 has been particularly harmful to patients with chronic kidney disease who are already facing many serious comorbidities," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We are sensitive to the needs of these patients and the health care providers who serve them. Even against the backdrop of a pandemic, we remain committed to truly make a difference in these patients' lives and potentially slow the inevitable progression of their underlying kidney disease."

Financial Results for the Three Months Ended March 31, 2020

Research and development expense was $49.4 million and $31.4 million for the three months ended March 31, 2020 and 2019, respectively. The increases in research and development expense in the three months ended March 31, 2020 compared to the three months ended March 31, 2019 were primarily due to increased activities in connection with our veverimer clinical development program, including manufacturing processes optimization, manufacturing of drug substance and drug product and our VALOR-CKD confirmatory postmarketing trial, and increased personnel and

related costs.

General and administrative expense was $23.5 million and $6.4 million for the three months ended March 31, 2020 and 2019, respectively. The increases in general and administrative expense in the three months ended March 31, 2020 compared to the three months ended March 31, 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 and professional service costs, and increased personnel and related costs.

Net loss was $74.1 million (non-GAAP net loss of $63.8 million) and $37.9 million (non-GAAP net loss of $34.4 million) for the three months ended March 31, 2020 and 2019, respectively. Net loss per basic and diluted share was $1.49 and $0.90 for the three months ended March 31, 2020 and 2019, respectively.

As of March 31, 2020, cash, cash equivalents and investments were $304.2 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 First 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:	**1674828**

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 timing for approval or commercial launch of veverimer, the assigned PDUFA goal date of August 22, 2020 and the scheduling of an advisory committee meeting, the potential availability of the Accelerated Approval Program, as well as the approvability of veverimer under that program, the therapeutic potential of, and potential clinical and commercial development plans for, veverimer, and the potential impact of COVID-19. 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 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 our Quarterly Reports on Form 10-Q and our Annual Report on Form 10-K. 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)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 10,555	$ 18,574
Short-term investments	273,738	289,424
Prepaid expenses and other current assets	5,496	4,744
Total current assets	289,789	312,742
Long-term investments	19,954	46,980
Property and equipment, net	1,420	2,728
Operating lease right-of-use assets	9,056	9,376
Total assets	$ 320,219	$ 371,826
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,994	$ 5,911
Current operating lease liabilities	1,080	1,072
Accrued expenses and other current liabilities	40,063	32,780
Total current liabilities	52,137	39,763
Term Loan	59,125	58,374
Non-current operating lease liabilities	8,650	8,783
Other long-term liabilities	1,846	1,023
Total liabilities	121,758	107,943

Stockholders' equity:		
Preferred stock	—	—
Common stock	50	50
Additional paid-in capital	641,571	632,647
Accumulated other comprehensive income (loss)	(39)	193
Accumulated deficit	(443,121)	(369,007)
Total stockholders' equity	198,461	263,883
Total liabilities and stockholders' equity	$ 320,219	$ 371,826

Tricida, Inc.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 49,381	$ 31,423
General and administrative	23,526	6,352
Total operating expenses	72,907	37,775
Loss from operations	(72,907)	(37,775)
Other income (expense), net	813	1,267
Interest expense	(2,020)	(1,389)
Net loss	(74,114)	(37,897)
Other comprehensive income (loss):		
Net unrealized gain (loss) on available-for-sale investments, net of tax	(232)	302
Total comprehensive loss	$ (74,346)	$ (37,595)

Net loss per share, basic and diluted	$ (1.49)	$ (0.90)
Weighted-average number of shares outstanding, basic and diluted	49,841,407	42,268,062

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 March 31,	
	2020	**2019**
GAAP net loss, as reported	$ (74,114)	$ (37,897)
Adjustments:		
Amortization of operating lease right-of-use assets	320	204
Stock-based compensation	8,374	2,658
Amortization of Term Loan discount and issuance costs	751	488
Changes in fair value of compound derivative liability	846	174
Total adjustments	10,291	3,524
Non-GAAP net loss	$ (63,823)	$ (34,373)

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) amortization of operating lease right-of-use assets, (2) stock-based compensation, (3) Amortization of Term Loan discount and issuance costs 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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