Tricida Announces Third Quarter 2019 Financial Results

November 14, 2019

FDA Accepts New Drug Application for Veverimer

Webcast Today at 4:30 pm Eastern Time

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 14, 2019-- 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 nine months ended September 30, 2019 and provided an update on key initiatives.

Recent Highlights

- Announced separately today that the U.S. Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) for veverimer under the Accelerated Approval Program. In its correspondence, FDA also stated that no filing review issues were identified. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 22, 2020 and indicated that it is currently planning to hold a Cardiovascular and Renal Drugs Advisory Committee (CRDAC) meeting to discuss the application.
- Continued enrolling patients in the VALOR-CKD postmarketing trial, with nearly 95% of the approximately 350 targeted sites open for enrollment. The VALOR-CKD postmarketing trial is currently estimated to complete enrollment in mid-2020.
- Expanded the metabolic acidosis disease awareness initiative at the American Society of Nephrology, or ASN, Kidney Week 2019 Meeting, engaging with over 1000 nephrologists and health care providers at Tricida's ASN Meeting booth to provide recent data on the serious consequences of metabolic acidosis and related topics. This level of engagement was more than double that achieved at Tricida's ASN Meeting booth in 2018.
- Sponsored four presentations at the ASN Kidney Week 2019 Meeting that reported real-world analyses from large databases of deidentified patient records:

– Metabolic Acidosis is Underdiagnosed and Undertreated in Patients with Chronic Kidney Disease.

– Metabolic Acidosis is Associated with Failure to Thrive and Fractures/Falls in Patients with Chronic Kidney Disease.

– Association of Metabolic Acidosis with Adverse Cardiovascular Outcomes in Patients with Chronic Kidney Disease.

– Metabolic Acidosis is an Independent Predictor of Adverse Renal Outcomes and Higher Costs in Patients with Chronic Kidney Disease.

- Presented at the ASN Kidney Week 2019 Meeting data on the mechanism of action of veverimer and the positive results from the TRCA-301E long-term extension trial that were also published in The Lancet in June 2019.

Upcoming Events and Projected Milestones

- Anticipated CRDAC meeting in the first half of 2020.
- Veverimer PDUFA goal date of August 22, 2020.
- Commercial launch of veverimer anticipated in the second half of 2020.

"We are pleased that our application for veverimer was accepted for review under the Accelerated Approval Program and look forward to engaging with experts at an advisory committee meeting," said Gerrit Klaerner, Ph.D., Tricida's chief executive officer and president. "With a potential approval in August 2020, veverimer would be the first and only FDA-approved therapy for the chronic treatment of metabolic acidosis in patients with CKD. Our commercial team is targeting a successful launch with a full quarter of revenue in the fourth quarter of 2020."

Financial Results for the Three and Nine Months Ended September 30, 2019

Research and development expense was $32.0 million and $25.2 million for the three months ended September 30, 2019 and 2018, respectively, and $92.4 million and $62.9 million for the nine months ended September 30, 2019 and 2018, respectively. The increases in research and development expense in the three and nine months ended September 30, 2019 compared to the prior year was primarily due to increased activities in connection with our veverimer clinical development program, including our VALOR-CKD confirmatory postmarketing trial, and increased personnel and related costs.

General and administrative expense was $13.1 million and $4.2 million for the three months ended September 30, 2019 and 2018, respectively, and $28.3 million and $11.9 million for the nine months ended September 30, 2019 and 2018, respectively. The increases in general and administrative expense in the three and nine months ended September 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, including pre-commercialization and professional service costs, and increased personnel and related costs.

Net loss was $44.1 million (non-GAAP net loss of $34.6 million) and $29.1 million (non-GAAP net loss of $27.0 million) for the three months ended September 30, 2019 and 2018, respectively, and $118.6 million (non-GAAP net loss of $100.4 million) and $75.0 million (non-GAAP net loss of $71.3 million) for the nine months ended September 30, 2019 and 2018, respectively. Net loss per basic and diluted share was $0.89 and $0.71 for the three months ended September 30, 2019 and 2018, respectively, and $2.53 and $4.86 for the nine months ended September 30, 2019 and 2018, respectively.

As of September 30, 2019, cash, cash equivalents and investments were $363.6 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 Third 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:	**4076109**

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 is currently conducting its confirmatory postmarketing trial, VALOR-CKD, of veverimer. The Tricida NDA for veverimer has been accepted for review by the FDA under 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, including for example, 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, such as the PDUFA goal date and advisory committee meeting, the conduct and expected enrollment milestones of our VALOR-CKD confirmatory postmarketing trial, and the potential availability of the Accelerated Approval Program, as well as 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 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 and manufacturers. 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 (SEC), 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.

Tricida, Inc.

Condensed Balance Sheets

(Unaudited)

(In thousands)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 30,368	$ 37,172
Short-term investments	291,864	203,906
Prepaid expenses and other current assets	4,856	3,269
Total current assets	327,088	244,347
Long-term investments	41,342	2,287
Property and equipment, net	2,053	1,215
Operating lease right-of-use assets	9,694	—
Total assets	$ 380,177	$ 247,849
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,471	$ 8,460
Current operating lease liabilities	1,064	—
Accrued expenses and other current liabilities	15,601	6,344
Total current liabilities	21,136	14,804
Term Loan	38,016	38,071
Non-current operating lease liabilities	8,914	—
Other long-term liabilities	488	449
Total liabilities	68,554	53,324
Stockholders' equity:		
Preferred stock	—	—

Common stock	50	42
Additional paid-in capital	621,923	386,830
Accumulated other comprehensive income (loss)	486	(153)
Accumulated deficit	(310,836)	(192,194)
Total stockholders' equity	311,623	194,525
Total liabilities and stockholders' equity	$ 380,177	$ 247,849

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,**	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 31,976	$ 25,230	$ 92,375	$ 62,897
General and administrative	13,120	4,178	28,333	11,888
Total operating expenses	45,096	29,408	120,708	74,785
Loss from operations	(45,096)	(29,408)	(120,708)	(74,785)
Other income (expense), net	2,387	1,247	6,256	1,987
Interest expense	(1,410)	(937)	(4,190)	(2,166)
Net loss	(44,119)	(29,098)	(118,642)	(74,964)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale investments	(143)	(14)	639	(27)
Total comprehensive loss	$ (44,262)	$ (29,112)	$ (118,003)	$ (74,991)
Net loss per share, basic and diluted	$ (0.89)	$ (0.71)	$ (2.53)	$ (4.86)
Weighted-average number of shares outstanding, basic and diluted	49,418,025	41,261,703	46,813,876	15,415,194

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,	
	2019	**2018**	**2019**	**2018**
GAAP net loss, as reported	$ (44,119)	$ (29,098)	$ (118,642)	$ (74,964)
Adjustments:				
Amortization of operating lease right-of-use assets	233	—	646	—
Stock-based compensation expense	8,682	1,706	15,753	3,029
Amortization of Term Loan discount and issuance costs	553	397	1,564	902
Changes in fair value of compound derivative liability and warrants	94	(2)	259	(238)
Total adjustments	9,562	2,101	18,222	3,693
Non-GAAP net loss	$ (34,557)	$ (26,997)	$ (100,420)	$ (71,271)

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) amortization of operating lease right-of-use assets, (2) stock-based compensation expense, (3) Amortization of Term Loan discount and issuance costs and (4) changes in fair value of compound derivative liability 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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Source: Tricida, Inc.

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