Tricida Announces Third Quarter 2020 Financial Results

November 9, 2020

SOUTH SAN FRANCISCO, Calif., Nov. 09, 2020 (GLOBE NEWSWIRE) -- Tricida, Inc. (Nasdaq: TCDA), a pharmaceutical company focused on the development and commercialization of its investigational 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, 2020 and provided an update on key initiatives.

Recent Events

- As previously announced on October 29, 2020, Tricida completed an End-of-Review Type A meeting with the FDA on October 20, 2020, that followed a Complete Response Letter (CRL) that was received by the company on August 21, 2020 for the veverimer New Drug Application (NDA) that was under review by the U.S. Food and Drug Administration (FDA) through the Accelerated Approval Program. Based on feedback during the Type A meeting, Tricida now believes the FDA will also require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program and that the FDA is unlikely to rely solely on serum bicarbonate data for determination of efficacy. Prior to the End-of-Review Type A meeting, over nearly four years, Tricida's discussions with the FDA focused on development of veverimer based solely on the use of serum bicarbonate as the surrogate endpoint to enable accelerated approval, with CKD progression data to be provided only at the completion of the VALOR-CKD trial. Tricida plans to wait for formal meeting minutes from the FDA related to the End-of-Review Type A meeting prior to determining how to proceed with obtaining regulatory approval for veverimer. The company expects to receive the formal minutes within 30 days from the meeting.

- Announced a re-organization of the company following the End-of-Review Type A meeting to extend its financial runway in order to maximize the options for bringing veverimer to patients. In this re-organization, the company is reducing its headcount from 152 to 59 employees and is discussing its commitments with vendors and contract service providers to potentially provide additional financial flexibility. The reduction in headcount will reduce Tricida's annual operating costs by approximately $25 million.

- Continued to enroll patients in its ongoing VALOR-CKD trial. The trial has enrolled over 1,200 of its planned 1,600 subjects. Based on feedback received from FDA, Tricida has elected to focus future VALOR-CKD enrollment activities in the US, Canada and 7 countries in Western Europe. It anticipates completing enrollment in the trial in 2022.

- Presented at the ASN Kidney Week 2020 Meeting real-world analyses from an Optum® de-identified Electronic Health Record dataset, 2007–2019, a longitudinal, clinical repository that includes 81 million de-identified patients from multiple large healthcare provider organizations across the United States. Results of the analyses of patients with CKD and with and without metabolic acidosis showed that:

  - Both baseline serum bicarbonate level and within-individual change in serum bicarbonate over time were significantly associated with differences in CKD progression as measured by time to ≥ 40% eGFR decline or progression by ≥ 1 CKD stage. Even small (1 mEq/L) increases in serum bicarbonate over time in patients with CKD were associated with significantly lower CKD progression rates.

  - Metabolic acidosis was a significant independent predictor of all-cause mortality in patients with CKD.

  - The presence of metabolic acidosis at baseline within every racial/ethnic group (Asian, Black, Hispanic, and non-Hispanic White) was independently associated with higher adjusted risk of death or adverse renal outcome.

  - In patients with advanced CKD, metabolic acidosis was associated with an increased adjusted risk of progression to dialysis or kidney transplantation. This increased risk was independent of age, sex, race, pre-existing comorbidities, baseline eGFR, and baseline urine albumin to creatinine ratio (ACR).

- Presented at the ASN Kidney Week 2020 Meeting data from veverimer safety and efficacy and drug-drug interaction trials, including:

  - New data describing the significant correlation between patient-reported limitations in daily activities as measured by the

Kidney Disease Quality of Life – Physical Function Domain and objectively measured physical function using the 5-times repeated chair stand test.

- Evaluation of data from sub-populations of the 52-week TRCA-301/TRCA-301E trial, including elderly patients, diabetic patients, and female patients, showing similar results to the overall findings in this trial.

- Evaluation of safety data from the 52-week TRCA-301/TRCA-301E trial demonstrating that, consistent with its mechanism of action as an orally administered, non-absorbed, counterion-free polymer, veverimer caused no adverse effects on volume status or blood pressure in patients with CKD and metabolic acidosis.

- Data evaluating the potential for drug interactions with veverimer showing that veverimer had no effect on the bioavailability of drugs most susceptible to direct binding to the polymer. Veverimer caused modest, transient increases in gastric pH, but had no effect on the bioavailability of drugs with pH-sensitive solubility. The effect of veverimer on gastric pH is similar in the presence or absence of omeprazole.

Upcoming Events

- Tricida anticipates receipt of the formal minutes from the End-of-Review Type A meeting within 30 days from the meeting.
- Tricida intends to provide a progress report to investors following receipt of the End-of-Review Type A meeting minutes to discuss the appropriate next steps toward its goal of obtaining FDA approval for veverimer.

“We believe the measures we have taken to re-organize our company will enable us to extend our operations to maximize our options to bring veverimer to patients,” said Gerrit Klaerner, Ph.D., Tricida’s Chief Executive Officer and President. “We look forward to a more detailed public communication prior to the end of the year, once we have formulated our regulatory strategy and determined our revised statistical analysis plan for VALOR-CKD, which will include one or more interim analyses for early stopping for efficacy.”

Financial Results for the Three and Nine Months Ended September 30, 2020

Research and development expense was $43.0 million and $32.0 million for the three months ended September 30, 2020 and 2019, respectively, and $121.1 million and $92.4 million for the nine months ended September 30, 2020 and 2019, respectively. The increase in research and development expense for the three months ended September 30, 2020 compared to the prior year was primarily due to increased activities in connection with our veverimer clinical development program related to manufacturing process optimization and the manufacturing of drug substance, partially offset by lower personnel costs. The increase in research and development expense for the nine months ended September 30, 2020 compared to the prior year was primarily due to increased activities in connection with our veverimer clinical development program related to manufacturing process optimization and the manufacturing of drug substance.

General and administrative expense was $29.3 million and $13.1 million for the three months ended September 30, 2020 and 2019, respectively, and $81.2 million and $28.3 million for the nine months ended September 30, 2020 and 2019, respectively. The increases in general and administrative expense in the three and nine months ended September 30, 2020 compared to the three and nine months ended September 30, 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, professional service costs and increased personnel costs.

Net loss was $77.7 million (non-GAAP net loss of $64.3 million) and $44.1 million (non-GAAP net loss of $34.6 million) for the three months ended September 30, 2020 and 2019, respectively, and $209.9 million (non-GAAP net loss of $177.0 million) and $118.6 million (non-GAAP net loss of $100.4 million) for the nine months ended September 30, 2020 and 2019, respectively. Net loss per basic and diluted share was $1.55 and $0.89 for the three months ended September 30, 2020 and 2019, respectively, and $4.20 and $2.53 for the nine months ended September 30, 2020 and 2019, respectively.

As of September 30, 2020, cash, cash equivalents and investments were $375.6 million.

Financial Guidance

Tricida is re-organizing the company to extend its financial runway in order to maximize the options for bringing veverimer to patients. The company will significantly reduce its headcount from 152 to 59 people and is discussing its commitments with vendors and contract service providers to potentially provide additional financial flexibility. This reduction in headcount will reduce Tricida’s annual operating costs by approximately $25 million. Based on its re-organization but prior to modifying any of its material vendor agreements, Tricida currently has the financial resources to fund its operations into at least mid-2022.

About Tricida

Tricida, Inc. is a pharmaceutical company focused on the development and commercialization of its investigational drug candidate, veverimer (also known as TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis in patients with CKD. There are no FDA-approved treatments for chronic metabolic acidosis. 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.

For more information about Tricida, please visit 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 of 1933 and Section 21E of the

Securities Exchange Act of 1934. 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 other statements, including the Company's plans and expectations with regard to its interactions and communications with the FDA, its plans and expectations as to the pathway to approval of veverimer by the FDA, including the potential availability of the Accelerated Approval Program, its plans and expectations for VALOR-CKD, and expectations regarding financial runway are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements. Such risks and uncertainties include, without limitation, the timing of the FDA's approval of veverimer, if at all; the potential availability of the Accelerated Approval Program and the approvability of veverimer under that program; the Company's plans and expectations with regard to its interactions with the FDA, including the potential resubmission of an NDA for veverimer; the Company's plans and expectations for future clinical and product development milestones; the Company's contractual and financial obligations to our key suppliers and vendors; the Company's financial projections and cost estimates; and risks associated with the Company's business prospects, financial results and business operations.

These and other factors that may affect the Company's future business prospects, results and operations are identified and described in more detail in the Company's filings with the Securities and Exchange Commission (the "SEC"), including the Company's most recent Annual Report filed on Form 10-K and the subsequently filed Quarterly Report(s) on Form 10-Q. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Except as required by applicable law, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

(Financial Tables to Follow)

Tricida, Inc.

Condensed Balance Sheets
(Unaudited)
(In thousands)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 29,712	$ 18,574
Short-term investments	288,284	289,424
Prepaid expenses and other current assets	8,063	4,744
Total current assets	326,059	312,742
Long-term investments	57,629	46,980
Property and equipment, net	1,782	2,728
Operating lease right-of-use assets	14,204	9,376
Total assets	$ 399,674	$ 371,826
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,787	$ 5,911
Current operating lease liabilities	1,822	1,072
Current Term Loan	13,714	—
Accrued expenses and other current liabilities	29,260	32,780
Total current liabilities	46,583	39,763
Non-current Term Loan, net	61,957	58,374
Convertible Senior Notes, net	116,625	—
Non-current operating lease liabilities	13,458	8,783
Other long-term liabilities	278	1,023
Total liabilities	238,901	107,943
Stockholders' equity:		
Preferred stock	—	—
Common stock	50	50
Additional paid-in capital	739,247	632,647
Accumulated other comprehensive income (loss)	432	193
Accumulated deficit	(578,956)	(369,007)
Total stockholders' equity	160,773	263,883
Total liabilities and stockholders' equity	$ 399,674	$ 371,826

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,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 42,996	$ 31,976	$ 121,134	$ 92,375
General and administrative	29,273	13,120	81,217	28,333
Total operating expenses	72,269	45,096	202,351	120,708
Loss from operations	(72,269)	(45,096)	(202,351)	(120,708)
Other income (expense), net	907	2,387	4,395	6,256
Interest expense	(6,267)	(1,410)	(12,043)	(4,190)
Loss before income taxes	(77,629)	(44,119)	(209,999)	(118,642)
Income tax benefit (expense)	(36)	—	50	—
Net loss	(77,665)	(44,119)	(209,949)	(118,642)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale investments, net of tax	(431)	(143)	239	639
Total comprehensive loss	$ (78,096)	$ (44,262)	$ (209,710)	$ (118,003)
Net loss per share, basic and diluted	$ (1.55)	$ (0.89)	$ (4.20)	$ (2.53)
Weighted-average number of shares outstanding, basic and diluted	50,120,086	49,418,025	49,974,388	46,813,876

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,	
	2020	**2019**	**2020**	**2019**
GAAP net loss, as reported	$ (77,665)	$ (44,119)	$ (209,949)	$ (118,642)
Adjustments:				
Non-cash operating lease costs	207	233	597	646
Accretion of Term Loan and Convertible Senior Notes	2,915	553	5,246	1,564
Stock-based compensation	7,655	8,682	25,108	15,753
Changes in fair value of compound derivative liability	(49)	94	(699)	259
Restructuring costs	2,660	—	2,660	—
Total adjustments	13,388	9,562	32,912	18,222
Non-GAAP net loss	$ (64,277)	$ (34,557)	$ (177,037)	$ (100,420)

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) non-cash operating lease costs, (2) accretion of Term Loan and Convertible Senior Notes, (3) stock-based compensation, (4) changes in fair value of compound derivative liability, and (5) restructuring costs, 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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