Tricida Announces Second Quarter 2021 Financial Results

August 9, 2021

Webcast Today at 4:30 pm Eastern Time

SOUTH SAN FRANCISCO, Calif., Aug. 09, 2021 (GLOBE NEWSWIRE) -- Tricida, Inc. (Nasdaq: TCDA), a pharmaceutical company focused on the development and commercialization of its investigational drug candidate, veverimer, a non-absorbed, orally-administered polymer designed to slow chronic kidney disease (CKD) progression in patients with metabolic acidosis and CKD, announced today financial results for the three and six months ended June 30, 2021 and provided an update on key initiatives.

Recent Events

- Tricida continues to execute on recruitment and conduct of the VALOR-CKD renal outcomes clinical trial. As of August 6, 2021, the VALOR-CKD trial had randomized 1,455 of the planned 1,600 subjects, with an average treatment duration of approximately 17 months and had accrued 127 of the 511 required subjects with a positively adjudicated primary endpoint event, defined as the time to first occurrence of renal death, end-stage renal disease (ESRD) or a confirmed greater than or equal to 40% reduction in eGFR (DD40). A pre-specified interim analysis for early stopping for efficacy of the VALOR-CKD trial is currently planned to occur when 250 events have been positively adjudicated by the independent blinded VALOR-CKD Clinical Endpoint Adjudication Committee. Tricida notes that a previously planned 150-event interim analysis has been removed from the VALOR-CKD trial protocol to preserve statistical and regulatory optionality.

- Tricida completed an updated assessment of the commercial market opportunity for veverimer based on anticipated outcomes data from the VALOR-CKD trial related to slowing CKD progression versus its prior market assessment which was based on surrogate biomarker data (i.e., serum bicarbonate). When shown a target product profile for veverimer which included DD40 outcomes data, physician respondents expressed a strong interest in prescribing veverimer, with over 90 percent of nephrologists and over 70 percent of non-nephrologists, including primary care physicians, cardiologists and endocrinologists, indicating that they “Definitely or Probably Would Prescribe Veverimer.” In addition, survey results indicate peak patient penetration for prescribing veverimer to be approximately 75% among nephrologists and over 55% among non-nephrologists.

- Tricida is assessing future development pathways for veverimer in an expanded population, including patients with CKD and latent acidosis. Latent acidosis, also known as eubicarbonatemic acidosis, describes a condition where the deleterious effects of acid accumulation may lead to impaired kidney, bone and muscle health prior to a decline in serum bicarbonate levels and a traditional diagnosis of metabolic acidosis.

Upcoming Milestones

- Tricida anticipates the VALOR-CKD trial pre-specified interim analysis for early stopping for efficacy in mid-2022, when 250 subjects are expected to have experienced DD40 events. If the independent unblinded Interim Analysis Committee does not recommend stopping the trial early for efficacy, Tricida will receive no information from this interim analysis.

“We continue to focus on our goal to generate outcome data from the VALOR-CKD trial, which we believe could serve as the basis for resubmission of our NDA,” said Gerrit Klaerner, Ph.D., Tricida’s Chief Executive Officer and President.

Financial Results for the Three and Six Months Ended June 30, 2021

Research and development expense was $19.8 million and $28.8 million for the three months ended June 30, 2021 and 2020, respectively. The decrease in research and development expense for the three months ended June 30, 2021 compared to the prior year was primarily due to decreased activities in connection with our veverimer clinical development program related to manufacturing process optimization and the manufacturing of drug substance and lower personnel costs. Research and development expense was $52.0 million and $78.1 million for the six months ended June 30, 2021 and 2020, respectively. The decrease in research and development expense for the six months ended June 30, 2021 compared to the prior year was primarily due to decreased activities in connection with our veverimer clinical development program related to manufacturing process optimization and the manufacturing of drug substance and lower personnel costs.

General and administrative expense was $9.6 million and $28.4 million for the three months ended June 30, 2021 and 2020, respectively. The decrease in general and administrative expense for the three months ended June 30, 2021 compared to the prior year was primarily due to decreased administrative activities in connection with our veverimer clinical development program, including pre-commercialization, medical affairs and personnel costs. General and administrative expense was $19.4 million and $51.9 million for the six months ended June 30, 2021 and 2020, respectively. The decrease in general and administrative expense for the six months ended June 30, 2021 compared to the prior year was primarily due to decreased administrative activities in connection with our veverimer clinical development program, including pre-commercialization, medical affairs and personnel costs.

Net loss was $33.6 million (non-GAAP net loss of $24.6 million) and $58.2 million (non-GAAP net loss of $48.9 million) for the three months ended June 30, 2021 and 2020, respectively, and $86.9 million (non-GAAP net loss of $62.9 million) and $132.3 million (non-GAAP net loss of $112.8 million) for the six months ended June 30, 2021 and 2020, respectively. Net loss per basic and diluted share was $0.67 and $1.16 for the three months ended June 30, 2021 and 2020, respectively, and $1.73 and $2.65 for the six months ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, cash, cash equivalents and investments were $175.8 million.

Financial Guidance

Tricida believes it has financial resources to fund its planned operations into late 2022. Based on the current rate of primary endpoint events in the VALOR-CKD trial, the 250-event interim analysis for early stopping for efficacy of the trial is expected to occur within the time frame of our existing capital. If we are compelled to stop the trial early for administrative reasons, that event could occur prior to the planned 250-event interim analysis.

Tricida Conference Call Information

Tricida will host its Second Quarter Financial Results and Business Update Conference Call and webcast today at 4:30 pm Eastern Time. The webcast and slide presentation or conference call may be accessed as follows:

Tricida Conference Call
Monday, August 9, 2021
4:30 pm Eastern Time

Webcast:	IR.Tricida.com
Dial-In:	**(877) 377-5478**
International:	(629) 228-0740
Conference ID:	**9679330**

A replay of the webcast will be available on 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 investigational drug candidate, veverimer (also known as TRC101), a non-absorbed, orally-administered polymer designed to slow CKD progression in patients with metabolic acidosis and CKD. Tricida is currently conducting a renal outcomes clinical trial, VALOR-CKD, to determine if veverimer slows CKD progression in patients with metabolic acidosis associated with CKD. Metabolic acidosis is a condition commonly caused by CKD that is believed to accelerate the progression of kidney deterioration. There are currently no therapies approved by the FDA to slow progression of kidney disease by correcting chronic metabolic acidosis in patients with CKD. 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 headings "Recent Events," "Upcoming Milestones" and "Financial Guidance" and other statements, including the Company's plans and expectations regarding event accrual rates for the VALOR-CKD renal outcomes clinical trial, its plans for interactions and communications with the FDA, its plans and expectations as to the pathway to approval of veverimer by the FDA, if at all, its assessment of potential clinical development pathways for veverimer, its assessment of the future market potential for veverimer and its 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 its key suppliers and vendors; the Company's financial projections and cost estimates; risks associated with the COVID-19 pandemic; risks associated with the Company's business prospects, financial results and business operations; risks related to the Company's ability to retain its key employees and executives; and risks related to the Company's capital requirements and ability to raise sufficient funds for its 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 (SEC), including the Company's most recent Annual Report filed on Form 10-K and its subsequently filed Quarterly Reports 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)

	June 30,	**December 31, 2020**

	2021	
Assets		
Current assets:		
Cash and cash equivalents	$ 22,865	$ 137,857
Short-term investments	152,901	171,670
Prepaid expenses and other current assets	5,261	4,488
Total current assets	181,027	314,015
Long-term investments	—	22,757
Property and equipment, net	934	1,112
Operating lease right-of-use assets	12,987	13,801
Total assets	$ 194,948	$ 351,685
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,738	$ 3,508
Current operating lease liabilities	2,608	2,079
Accrued expenses and other current liabilities	19,522	28,671
Total current liabilities	24,868	34,258
Term Loan, net	—	76,638
Convertible Senior Notes, net	122,951	118,670
Non-current operating lease liabilities	12,200	13,046
Other long-term liabilities	—	202
Total liabilities	160,019	242,814
Stockholders' equity:		
Preferred stock	—	—
Common stock	50	50
Additional paid-in capital	755,654	742,555
Accumulated other comprehensive income (loss)	(62)	64
Accumulated deficit	(720,713)	(633,798)
Total stockholders' equity	34,929	108,871
Total liabilities and stockholders' equity	$ 194,948	$ 351,685

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 19,781	$ 28,757	$ 51,956	$ 78,138
General and administrative	9,550	28,418	19,445	51,944
Total operating expenses	29,331	57,175	71,401	130,082
Loss from operations	(29,331)	(57,175)	(71,401)	(130,082)
Other income (expense), net	(296)	2,675	149	3,488
Interest expense	(3,926)	(3,756)	(9,539)	(5,776)
Loss on early extinguishment of Term Loan	—	—	(6,124)	—
Loss before income taxes	(33,553)	(58,256)	(86,915)	(132,370)
Income tax benefit (expense)	—	86	—	86
Net loss	(33,553)	(58,170)	(86,915)	(132,284)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale investments, net of tax	(21)	902	(126)	670
Total comprehensive loss	$ (33,574)	$ (57,268)	$ (87,041)	$ (131,614)
Net loss per share, basic and diluted	$ (0.67)	$ (1.16)	$ (1.73)	$ (2.65)
Weighted-average number of shares outstanding, basic and diluted	50,294,787	49,960,072	50,271,373	49,900,739

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,	
	2021	**2020**	**2021**	**2020**
GAAP net loss, as reported	$ (33,553)	$ (58,170)	$ (86,915)	$ (132,284)
Adjustments:				
Non-cash operating lease costs	248	70	496	390
Accretion of Term Loan and Convertible Senior Notes	2,176	1,580	4,804	2,331
Loss on early extinguishment of Term Loan	—	—	6,124	—
Stock-based compensation	6,609	9,079	12,651	17,453
Changes in fair value of compound derivative liability	—	(1,496)	(202)	(650)
Restructuring costs	(113)	—	107	—
Total adjustments	8,920	9,233	23,980	19,524
Non-GAAP net loss	$ (24,633)	$ (48,937)	$ (62,935)	$ (112,760)

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) loss on early extinguishment of Term Loan, (4) stock-based compensation, (5) changes in fair value of compound derivative liability and (6) 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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