Tricida Announces Fourth Quarter and Full Year 2020 Financial Results

February 25, 2021

SOUTH SAN FRANCISCO, Calif., Feb. 25, 2021 (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 fourth quarter and year ended December 31, 2020 and provided an update on key initiatives.

Recent Events

- As announced separately today, Tricida has received an Appeal Denied Letter (ADL) from the Office of New Drugs (OND) of the U.S. Food and Drug Administration (FDA) in response to its Formal Dispute Resolution Request (FDRR).
- Tricida continues to effectively execute on VALOR-CKD trial recruitment and conduct. As of February 22, 2021, the VALOR-CKD trial has randomized 1,433 of 1,600 subjects with an average treatment duration of approximately one year and has accrued 69 of the 511 required subjects with positively adjudicated primary endpoint events.
- Tricida announced that Geoffrey Parker, Chief Financial Officer and Executive Vice President has been promoted to the newly created role of Chief Operating Officer, Chief Financial Officer and Executive Vice President. In his expanded role, Mr. Parker will continue to lead all finance and accounting activities and additionally focus on corporate and business development strategies.

2020 Key Events

Tricida's key events and activities in 2020 include:

- Received a Complete Response Letter (CRL) for its veverimer New Drug Application (NDA) in August 2020;
- Held an End-of-Review Type A meeting in response to the CRL in October 2020;
- Submitted the FDRR to the OND in December 2020;
- Restructured the company in the second half of 2020 in order to maximize the options for bringing veverimer to patients;
- Presented or published 20 peer-reviewed posters or articles that highlight veverimer, the serious complications of metabolic acidosis and its economic burden to the healthcare system;
- Engaged with 126 payers representing approximately 310 million lives to evaluate coverage of veverimer, if approved, provide information about the design and results of our health economic study and share veverimer clinical trial data;
- Expanded metabolic acidosis disease education and awareness through the sponsorship of Continuing Medical Education (CME) programs, and enhanced educational materials available through the MetabolicAcidosisInsights.com website;
- Continued successful execution on its global IP strategy, resulting in the allowance of a U.S. patent application that, upon issuance in 2021 will extend protection for veverimer to 2038 in the U.S., and the issuance of an additional 126 patents in 47 different countries, including Australia, China, Israel, Japan, Russia and numerous European and European extension states; and
- Issued, in May 2020, $200 million aggregate principal amount of 3.50% convertible senior notes due 2027, securing additional capital to fund operations.

"We accomplished a great deal in 2020 but were obviously disappointed that we could not launch veverimer as the first and only FDA-approved treatment for chronic metabolic acidosis in patients with CKD," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We will now focus on the VALOR-CKD trial to generate additional data prior to the end of 2022."

Upcoming Milestones

- Anticipate the first VALOR-CKD renal outcomes trial interim analysis for early stopping for efficacy in the second half of

2021 when 150 primary renal endpoint events are expected to have accrued. A primary endpoint event in the VALOR-CKD trial is defined as renal death, end-stage renal disease (ESRD) or a confirmed ≥ 40% reduction in estimated glomerular filtration rate (eGFR), also known as DD40. If the independent unblinded Interim Analysis Committee does not recommend stopping the trial early for efficacy, we will receive no information from this interim analysis.

- Anticipate the second VALOR-CKD renal outcomes trial interim analysis for early stopping for efficacy in mid-2022 when 250 primary renal endpoint events are expected to have accrued. If the independent unblinded Interim Analysis Committee does not recommend stopping the trial early for efficacy, we will receive no information from this interim analysis.

- Prior to the end of 2022, the company will also evaluate options with a focus on obtaining additional data from the VALOR-CKD trial on the effects of veverimer on (1) CKD progression; (2) physical functioning; and (3) serum bicarbonate. These options include the possibility of stopping the trial early for administrative reasons, which would allow analysis of the data using all alpha remaining at that time.

Financial Results for the Three Months and Year Ended December 31, 2020

Research and development expense was $27.3 million and $40.7 million for the three months ended December 31, 2020 and 2019, respectively, and $148.4 million and $133.0 million for the years ended December 31, 2020 and 2019, respectively. The decrease in research and development expense for the three months ended December 31, 2020 compared to the prior year was primarily due to a decrease in activities in connection with our veverimer clinical development program related to manufacturing process optimization and the manufacturing of drug substance and lower personnel costs. The increase in research and development expense for the year ended December 31, 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.

General and administrative expense was $21.8 million and $17.5 million for the three months ended December 31, 2020 and 2019, respectively, and $103.0 million and $45.8 million for the years ended December 31, 2020 and 2019, respectively. The increase in general and administrative expense for the three months ended December 31, 2020 compared to the prior year was primarily due to restructuring costs including one-time termination severance payments and contract termination costs, partially offset by lower pre-commercialization and other administrative costs due to a decrease in activities in connection with our veverimer clinical development program. The increase in general and administrative expense for the year ended December 31, 2020 compared to the prior year was primarily due to increased pre-commercialization and associated administrative activities in connection with our veverimer clinical development program and restructuring costs including one-time termination severance payments and contract termination costs.

Net loss was $54.8 million (non-GAAP net loss of $33.0 million) and $58.2 million (non-GAAP net loss of $47.3 million) for the three months ended December 31, 2020 and 2019, respectively, and $264.8 million (non-GAAP net loss of $214.4 million) and $176.8 million (non-GAAP net loss of $147.7 million) for the years ended December 31, 2020 and 2019, respectively. Net loss per basic and diluted share was $1.09 and $1.17 for the three months ended December 31, 2020 and 2019, respectively, and $5.29 and $3.72 for the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, cash, cash equivalents and investments were $332.3 million.

Financial Guidance

Tricida currently has the financial resources to fund its operations into at least mid-2022, prior to modifying any of its material agreements. Discussions are ongoing to modify certain of these agreements and, if successful, would extend the company's financial resources beyond mid-2022. Tricida plans to obtain additional data on the effect of veverimer on (1) CKD progression; (2) physical functioning; and (3) serum bicarbonate within the time frame of our existing capital resources.

Tricida Conference Call Information

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

Tricida Conference Call
Thursday, February 25, 2021
4:30 pm Eastern Time

Webcast:	**IR.Tricida.com**
Dial-In:	**(800) 773-2954**
International:	(847) 413-3731
Conference ID:	**50111253**

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 treat metabolic acidosis in patients with 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. 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 Milestones" and other statements, including the Company's plans and expectations for VALOR-CKD, its interactions and communications with the FDA, its plans and expectations as to the pathway to approval of veverimer by the FDA, if at all, including the potential availability of the Accelerated Approval Program, 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 our key suppliers and vendors; the Company's financial projections and cost estimates; risks associated with the COVID-19 pandemic; 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 (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)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 137,857	$ 18,574
Short-term investments	171,670	289,424
Prepaid expenses and other current assets	4,488	4,744
Total current assets	314,015	312,742
Long-term investments	22,757	46,980
Property and equipment, net	1,112	2,728
Operating lease right-of-use assets	13,801	9,376
Total assets	$ 351,685	$ 371,826
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,508	$ 5,911
Current operating lease liabilities	2,079	1,072
Accrued expenses and other current liabilities	28,671	32,780
Total current liabilities	34,258	39,763
Term Loan, net	76,638	58,374
Convertible Senior Notes, net	118,670	—
Non-current operating lease liabilities	13,046	8,783
Other long-term liabilities	202	1,023
Total liabilities	242,814	107,943
Stockholders' equity:		
Preferred stock	—	—
Common stock	50	50
Additional paid-in capital	742,555	632,647
Accumulated other comprehensive income (loss)	64	193
Accumulated deficit	(633,798)	(369,007)
Total stockholders' equity	108,871	263,883

Total liabilities and stockholders' equity	$ 351,685	$ 371,826

Tricida, Inc.

Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Years Ended December 31,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 27,283	$ 40,653	$ 148,417	$ 133,028
General and administrative	21,766	17,463	102,983	45,796
Total operating expenses	49,049	58,116	251,400	178,824
Loss from operations	(49,049)	(58,116)	(251,400)	(178,824)
Other income (expense), net	621	1,407	5,016	7,663
Interest expense	(6,364)	(1,554)	(18,407)	(5,744)
Loss before income taxes	(54,792)	(58,263)	(264,791)	(176,905)
Income tax benefit (expense)	(50)	92	—	92
Net loss	(54,842)	(58,171)	(264,791)	(176,813)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale investments, net of tax	(368)	(293)	(129)	346
Total comprehensive loss	$ (55,210)	$ (58,464)	$ (264,920)	$ (176,467)
Net loss per share, basic and diluted	$ (1.09)	$ (1.17)	$ (5.29)	$ (3.72)
Weighted-average number of shares outstanding, basic and diluted	50,186,615	49,620,063	50,027,735	47,521,237

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 December 31,		Years Ended December 31,	
	2020	**2019**	**2020**	**2019**
GAAP net loss, as reported	$ (54,842)	$ (58,171)	$ (264,791)	$ (176,813)
Adjustments:				
Non-cash operating lease costs	207	318	845	964
Accretion of Term Loan and Convertible Senior Notes	2,915	609	8,258	2,173
Stock-based compensation	7,655	9,415	28,298	25,168
Changes in fair value of compound derivative liability	(49)	557	(775)	816
Restructuring costs	11,089	—	13,749	—
Total adjustments	21,817	10,899	50,375	29,121
Non-GAAP net loss	$ (33,025)	$ (47,272)	$ (214,416)	$ (147,692)

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 (cash and non-cash), 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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