

# TCR<sup>2</sup> Therapeutics Reports First Quarter 2021 Financial Results and Provides Corporate Update

# May 13, 2021

CAMBRIDGE, Mass., May 13, 2021 (GLOBE NEWSWIRE) -- TCR<sup>2</sup> Therapeutics Inc. (Nasdaq: TCRR), a clinical-stage cell therapy company with a pipeline of novel T cell therapies for patients suffering from cancer, today announced financial results for the first quarter ended March 31, 2021 and provided a corporate update.

"We remain on track to identify the recommended Phase 2 dose for gavo-cel in 2021 and advance into the expansion portion of the Phase 1/2 trial where our primary focus will be efficacy as well as continuing to monitor for safety. The clinical benefit we have observed with our cancer patients gave us confidence to expand our manufacturing capabilities by establishing a commercial-scale cGMP facility in Rockville, Maryland, which we expect to come online in 2023," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR<sup>2</sup> Therapeutics. "In the last quarter we were also able to showcase our early-stage programs in our rich pipeline and reflect on the versatility of our TRuC-T cell platform. This included presenting our CD70-targeted autologous TRuC-T cell and our mesothelin-targeted allogeneic TRuC-T cell at AACR. As for our additional solid tumor milestones in 2021, we expect to present more complete data from the dose escalation Phase 1 portion of the gavo-cel trial, file an IND for TC-510, a mesothelin-targeted TRuC-T cell enhanced with a PD-1:CD28 switch receptor, and present preclinical data on our IL-15 enhancement, which we believe will drive even longer persistence and expression of a memory phenotype, characteristics which could be beneficial across our portfolio."

## **Recent Developments**

gavo-cel:

 TCR<sup>2</sup> presented clinical and translational data from the dose escalation portion of the Company's Phase 1/2 clinical trial of gavo-cel in patients with treatment refractory mesothelin-expressing solid tumors at the American Association for Cancer Research (AACR) Virtual Annual Meeting. The data reported were from eight treatment-refractory mesothelin-expressing solid tumor patients and highlighted translational markers consistent with the clinical profile, including transduction efficiency, CD4:CD8 ratio, memory phenotype, expansion and persistence and cytokines.

# Early-Stage Pipeline

- TCR<sup>2</sup> presented new preclinical data from its allogeneic "off the shelf" TRuC-T cell targeting mesothelin highlighting a lack of alloreactivity, reduced risk of host rejection, upregulation of activation markers, secretion of cytokines and clearance of tumors comparable to gavo-cel at the AACR Virtual Annual Meeting.
- TCR<sup>2</sup> presented new preclinical data from its TRuC-T cell targeting CD70 highlighting T cell expansion, improved memory phenotype, significant anti-tumor efficacy in multiple xenograft mouse models with no evidence of *in vivo* fratricide at the AACR Virtual Annual Meeting.

## Corporate:

- TCR<sup>2</sup> announced that it signed a long-term, full-building lease with Alexandria Real Estate Equities, Inc. (NYSE: ARE) for an existing 85,000 square foot cell therapy manufacturing facility in Rockville, Maryland which is ready for Current Good Manufacturing Practice (cGMP) build-out. The site will support clinical and commercial production of gavo-cel with a capacity that is projected to treat several thousand cancer patients annually. The facility is expected to accelerate the Company's commercial-scale manufacturing timelines with production anticipated in 2023.
- TCR<sup>2</sup> announced the appointment of Aaron Vernon as Vice President of Technical Operations. Previously, Mr. Vernon held senior positions including Vice President of Global Technical Operations and Vice President of Engineering & Supply Chain at Autolus Therapeutics, where he led manufacturing capacity expansion and overseeing internal and external manufacturing of plasmid, vector and cell therapy products.

## **Anticipated Milestones**

• TCR<sup>2</sup> to present additional safety, efficacy and translational data from the Phase 1 portion of the gavo-cel Phase 1/2

clinical trial for patients with mesothelin-expressing solid tumors throughout 2021.

- TCR<sup>2</sup> to present an interim update from the Phase 1 portion of the TC-110 Phase 1/2 clinical trial for patients with CD19+ non-Hodgkin lymphoma or adult acute lymphoblastic leukemia in the second half of 2021.
- TCR<sup>2</sup> plans to file an IND for TC-510, the first enhanced TRuC-T cell targeting mesothelin with a PD-1:CD28 switch, in the second half of 2021.
- TCR<sup>2</sup> plans to select a development candidate for its allogeneic program in the second half of 2021.
- TCR<sup>2</sup> to present preclinical data on its IL-15 enhancements program in the second half of 2021.
- TCR<sup>2</sup> anticipates production of clinical trial material from ElevateBio LLC and its manufacturing facility in Stevenage, UK, both in anticipation of demand from the Phase 2 expansion trial of gavo-cel, in 2022.

## **Financial Highlights**

- Cash Position: TCR<sup>2</sup> ended the first quarter of 2021 with \$333.3 million in cash, cash equivalents, and investments compared to \$228.0 million as of December 31, 2020. Net cash used in operations was \$19.9 million for the first quarter of 2021 compared to \$16.4 million for the first quarter of 2020. TCR<sup>2</sup> projects net cash use of \$100-110 million for 2021, which includes tenant improvements to the Rockville facility. We expect cash on hand to support operations through 2023.
- R&D Expenses: Research and development expenses were \$15.9 million for the first quarter of 2021 compared to \$12.0 million for the first quarter of 2020. The increase in R&D expenses is primarily related to ongoing clinical trials, increase in headcount and additional lab facilities.
- **G&A Expenses**: General and administrative expenses were \$5.7 million for the first quarter of 2021 compared to \$4.3 million for the first quarter of 2020. The increase in general and administrative expenses was primarily due to an increase in personnel costs.
- Net Loss: Net loss was \$21.5 million for the first quarter of 2021 compared to \$15.5 million for the first quarter of 2020, driven predominantly by increased personnel expenses.

#### **Rockville Facility**

In March 2021, we entered into a lease for a new manufacturing facility. The landlord built an approximately 85,000 square foot rental building in Rockville, Maryland and leased the facility to the Company as a manufacturing facility for an initial term of 15 years through June 2036.

Because we are involved in the construction project and are responsible for paying a significant portion of the costs of normal finish work and structural elements of the facility, the Company is deemed for accounting purposes to be the owner of the building during the construction period under build to suit lease accounting guidance under ASC 840, Leases. Therefore, the Company recorded a construction-in-progress asset and a related construction financing obligation on our consolidated balance sheets as a component of property and equipment and lease financing obligations, respectively. We anticipate lease payments of \$1.4 million for the remainder of 2021.

## About TCR<sup>2</sup> Therapeutics

TCR<sup>2</sup> Therapeutics Inc. is a clinical-stage cell therapy company developing a pipeline of novel T cell therapies for patients suffering from solid tumors or hematological malignancies. TCR<sup>2</sup>s proprietary T cell receptor (TCR) Fusion Construct T cells (TRuC<sup>®</sup>-T cells) specifically recognize and kill cancer cells by harnessing signaling from the entire TCR, independent of human leukocyte antigens (HLA). In preclinical studies, TRuC-T cells have demonstrated superior anti-tumor activity compared to chimeric antigen receptor T cells (CAR-T cells), while secreting lower levels of cytokine release. The Company's lead TRuC-T cell product candidate targeting solid tumors, gavo-cel, is currently being studied in a Phase 1/2 clinical trial to treat patients with mesothelin-positive non-small cell lung cancer (NSCLC), ovarian cancer, malignant pleural/peritoneal mesothelioma, and cholangiocarcinoma. The Company's lead TRuC-T cell product candidate targeting hematological malignancies, TC-110, is currently being studied in a Phase 1/2 clinical trial to treat patients with CD19-positive adult acute lymphoblastic leukemia (aALL) and with aggressive or indolent non-Hodgkin lymphoma (NHL). For more information about TCR<sup>2</sup>, please visit www.tcr2.com.

#### **Forward-looking Statements**

This press release contains forward-looking statements and information within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "will," "could", "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "seeks," "endeavor," "potential," "continue" or the negative of such words or other similar expressions can be used to identify forward-looking statements. These forward-looking statements include, but are not limited to, express or implied statements regarding the therapeutic potential of gavo-cel, timing for interim updates for the gavo-cel and TC-110 clinical trials, timing for the certification of our manufacturing facility in Stevenage, UK and Rockville, MD, increased manufacturing capacity and technical capabilities, including relating to our manufacturing partnership with ElevateBio, LLC, increased clinical trial demand, future IND filings and clinical development plans, the development of the Company's TRuC-T cells, their potential characteristics, applications and clinical utility, and the potential therapeutic applications of the Company's TRuC-T cell platform.

The expressed or implied forward-looking statements included in this press release are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation: uncertainties inherent in clinical studies and in the availability and timing of data from ongoing clinical studies; whether interim results from a clinical trial will be predictive of the final results of the trial; whether results from preclinical studies or earlier clinical studies will be predictive of the results; the expected timing of submissions for regulatory approval or review by

governmental authorities, including review under accelerated approval processes; orphan drug designation eligibility; regulatory approvals to conduct trials or to market products; TCR<sup>2</sup>s ability to maintain sufficient manufacturing capabilities to support its research, development and commercialization efforts, including TCR<sup>2</sup>s ability to secure additional manufacturing facilities; whether TCR <sup>2</sup>'s cash resources will be sufficient to fund TCR<sup>2</sup>'s foreseeable and unforeseeable operating expenses and capital expenditure requirements, the impact of the COVID-19 pandemic on TCR<sup>2</sup>'s ongoing operations; and other risks set forth under the caption "Risk Factors" in TCR<sup>2</sup>'s most recent Annual Report on Form 10-K, most recent Quarterly Report on Form 10-Q and its other filings with the Securities and Exchange Commission. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although TCR<sup>2</sup> believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur.

Moreover, except as required by law, neither TCR<sup>2</sup> nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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# TCR<sup>2</sup> THERAPEUTICS INC. UNAUDITED CONSOLIDATED BALANCE SHEETS (amounts in thousands, except share data)

		December 31, 2020	
Assets			
Current assets			
Cash and cash equivalents	\$ 218,276	\$ 94,155	
Investments	115,005	133,831	
Prepaid expenses and other current assets	9,690	7,552	
Total current assets	342,971	235,538	
Property and equipment, net	51,842	10,013	
Restricted cash	1,141	583	
Deferred offering costs	225	61	
Total assets	\$ 396,179	\$ 246,195	
Liabilities and stockholders' equity			
Accounts payable	\$ 3,830	\$ 2,448	
Accrued expenses and other current liabilities	4,577	6,392	
Lease financing obligation	2,114		
Total current liabilities	10,521	8,840	
Lease financing obligation, excluding current portion	35,011		
Other liabilities	892	807	
Total liabilities	46,424	9,647	
Stockholders' equity			
Common stock, \$0.0001 par value; 150,000,000 shares authorized; 38,159,202 and 24,050,936 shares issued; 38,159,202 and			
23,981,109 shares outstanding at December 31, 2020 and 2019, respectively.	4	3	
Additional paid-in capital	621,022	486,197	
Accumulated other comprehensive income	(44)	63	
Accumulated deficit	(271,227)	(249,715	
Total stockholders' equity	349,755	236,548	
Total liabilities and stockholders' equity	\$ 396,179	\$ 246,195	

### TCR<sup>2</sup> THERAPEUTICS INC.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

(amounts in thousands, except share and per share data)

**Three Months Ended** 

	March 31,			
	2021	2020		
Operating expenses				
Research and development	\$ 15,924	\$ 11,955		
General and administrative	5,668	4,271		
Total operating expenses	21,592	16,226		
Loss from operations	(21,592	) (16,226)		
Interest income, net	116	747		
Loss before income tax expense	(21,476	) (15,479)		
Income tax expense	36	27		
Net loss	\$ (21,512	) \$ (15,506)		
Per share information				
Net loss per share of common stock, basic and diluted	\$ (0.58	) <u>\$ (0.65</u> )		
Weighted average shares outstanding, basic and diluted	37,062,604	24,011,843		

# TCR<sup>2</sup> THERAPEUTICS INC. UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)

	Three Months Ended March 31,			
		2021		2020
Operating activities				
Net loss	\$	(21,512)	\$	(15,506)
Adjustments to reconcile net loss to cash used in operating activities:				
Depreciation and amortization		513		306
Stock-based compensation expense		3,120		2,055
Accretion on investments		164		(164)
Deferred tax liabilities		36		-
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets		(2,136)		(1,589)
Accounts payable		1,684		603
Accrued expenses and other liabilities		(1,767)		(2,115)
Cash used in operating activities		(19,898)		(16,410)
Investing activities				
Purchases of equipment		(1,491)		(504)
Purchases of investments		(40,732)		(47,956)
Proceeds from sale or maturity of investments		59,287		30,617
Cash used in investing activities		17,064		(17,843)
Financing activities				
Proceeds from public offering of common stock, net of issuance costs		131,330		-
Proceeds from the exercise of stock options		376		185
Payments on lease financing obligation		(4,029)		-
Deferred offering costs		(164)		(135)
Cash provided by financing activities		127,513		50
Net change in cash, cash equivalents, and restricted cash		124,679		(34,203)
Cash, cash equivalents, and restricted cash at beginning of year		94,738		65,713
Cash, cash equivalents, and restricted cash at end of period	\$	219,417	\$	31,510



Source: TCR2 Therapeutics