

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):  
May 13, 2021

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

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-38811

(Commission File Number)

47-4152751

(I.R.S Employer Identification No.)

100 Binney Street

Suite 710 Cambridge MA  
(Address of Principal Executive Offices)

02142  
(Zip Code)

(617) 949-5200

(Registrant's telephone number, including area code)

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	TCRR	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

## Item 2.02 Results of Operations and Financial Condition

On May 13, 2021, TCR<sup>2</sup> Therapeutics Inc. announced its financial results for the fiscal quarter ended March 31, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Report on Form 8-K, including Exhibit 99.1, attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release dated May 13, 2021</a>
104	Inline XBRL cover page

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## Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 13, 2021

**TCR<sup>2</sup> Therapeutics Inc.**

By: /s/ Mayur (Ian) Somaiya

Mayur (Ian) Somaiya  
Chief Financial Officer



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

**CAMBRIDGE, Mass.**, May 13, 2021 - 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
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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

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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 TCR2 Therapeutics**

TCR2 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. TCR2's proprietary T cell receptor (TCR) Fusion Construct T cells (TRuC®-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 TCR2, please visit [www.tcr2.com](http://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 of future trials; 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; TCR2's ability to maintain sufficient manufacturing capabilities to support its research, development and commercialization efforts, including TCR2's ability to secure additional manufacturing facilities; whether TCR2's cash resources will be sufficient to fund TCR2's foreseeable and unforeseeable operating expenses and capital expenditure requirements, the impact of the COVID-19 pandemic on TCR2's ongoing operations; and other risks set forth under the caption "Risk Factors" in TCR2'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 TCR2 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.

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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.

**Investor and Media Contact:**

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

	March 31, 2021	December 31, 2020
<b>Assets</b>		
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	<u>\$ 396,179</u>	<u>\$ 246,195</u>
<b>Liabilities and stockholders' equity</b>		
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	<u>\$ 396,179</u>	<u>\$ 246,195</u>



**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)	\$ (0.65)
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
<b>Operating activities</b>		
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	<u>(19,898)</u>	<u>(16,410)</u>
<b>Investing activities</b>		
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	<u>17,064</u>	<u>(17,843)</u>
<b>Financing activities</b>		
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	<u>127,513</u>	<u>50</u>
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	<u>\$ 219,417</u>	<u>\$ 31,510</u>

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