

**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 14, 2020**

TCR² 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 14, 2020, TCR² Therapeutics Inc. announced its financial results for the quarter ended March 31, 2020. 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	Press release dated May 14, 2020
104	Inline XBRL cover page

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 14, 2020

TCR² Therapeutics Inc.

By: /s/ Mayur (Ian) Somaiya
Mayur (Ian) Somaiya
Chief Financial Officer



TCR² Therapeutics Reports First Quarter 2020 Financial Results and Provides Corporate Update

- Continued progress on treatment of TC-210 patients with interim update from Phase 1 portion of Phase 1/2 clinical trial anticipated in mid-2020
- Continued progress of TC-110 with initiation of leading clinical sites participating in Phase 1/2 clinical trial that include Sarah Cannon Research Institute and Colorado Blood Cancer Institute
- TC-110 granted orphan drug designation for the treatment of acute lymphoblastic leukemia
- Nomination of third mono TRuC program targeting CD70 with anticipated IND filing in 1H21
- Two new appointments to the Board of Directors: immuno-oncology pioneer Dr. Axel Hoos and veteran finance executive Stephen Webster
- Cash position of \$141M provides sufficient runway into 2022

CAMBRIDGE, Mass., May 14, 2020 - TCR² Therapeutics Inc. (Nasdaq: TCRR), a clinical-stage immunotherapy company developing the next generation of novel T cell therapies for patients suffering from cancer, today announced financial results for the first quarter ended March 31, 2020 and provided a corporate update.

"Based on our clinical progress to date and a growing confidence in our TRuC platform, we are advancing a third mono TRuC-T cell candidate targeting CD70, a clinically validated target which will allow us to make further inroads into both solid tumors and hematological malignancies," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. "In addition, the expression of CD70 in tumors where CD19 and mesothelin are overexpressed represents a good opportunity for our dual TRuCs. With this new program and the strengthening of our Board with the appointments of Axel Hoos and Stephen Webster, we are well-positioned to deliver on the near- and long-term value opportunities of our platform as we approach data for our lead assets in 2020."

"Despite steps taken to protect our lead programs from the impact of COVID-19, we are updating our TC-210 guidance to expect an interim update from the Phase 1 portion in mid-2020, allowing for additional time to work with clinical investigators and patients on activities that require visits to clinical sites, including data monitoring. We look forward to presenting on the efficacy, safety and translational data in the very near future," added Dr. Menzel.

Recent Developments

- The U.S. Food and Drug Administration granted orphan drug designation to TC-110 for the treatment of acute lymphoblastic leukemia.
 - TCR² nominated a CD70 targeted TRuC-T cell product candidate designed to treat patients with either hematological malignancies or solid tumors, including potential indications such as acute myeloid leukemia, non-Hodgkin lymphoma, renal cell carcinoma, nasopharyngeal cancer, glioblastoma, and malignant pleural/peritoneal mesothelioma.
 - TCR² announced the appointment of Axel Hoos, M.D., Ph.D., to its Board of Directors. Dr. Axel Hoos is Senior Vice President, R&D Governance Chair, and Therapeutic Area Head for Oncology at GlaxoSmithKline Pharmaceuticals. He is responsible for technical and funding decisions and leads the Oncology business including discovery and development with the four focus areas of immuno-oncology, epigenetics, cell & gene therapy and synthetic lethality.
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- TCR² announced the appointment of Stephen Webster to its Board of Directors. Mr. Stephen Webster served as Chief Financial Officer of Spark Therapeutics until its acquisition by Roche and brings nearly 30 years of experience in raising capital, business development transactions and operations.

COVID-19 Update

- As the Company balances the commitment to treat our cancer patients while mitigating the risk of viral spread to patients, employees and their families, TCR² has instituted protective policies consistent with guidelines provided by the Centers for Disease Control and Prevention at all TCR² facilities.
- COVID-19 has significantly impacted the global healthcare system, including the conduct of clinical trials as medical institutions prioritize the treatment of those afflicted with COVID-19. TCR² continues to closely monitor the adverse impact of the COVID-19 pandemic on operations and ongoing clinical and preclinical development.
- While the Company believes it has been able, to date, to mitigate some of the impact from the COVID-19 pandemic on its ongoing clinical programs, the Company is committed to providing an interim update of the Phase 1 portion of the TC-210 Phase 1/2 clinical trial in mid-2020 and the Phase 1 portion of the TC-110 Phase 1/2 clinical trial in the second half of 2020.

Anticipated Milestones

- TCR² anticipates an interim update from the Phase 1 portion of the TC-210 Phase 1/2 clinical trial for patients with mesothelin-expressing solid tumors in mid-2020.
- TCR² anticipates 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 2H20.
- TCR² anticipates clinical production of TRuC-T cells at its manufacturing facility in Stevenage, UK, in 2H20.
- TCR² anticipates a target IND filing for the third mono TRuC-T cell program targeting CD70 in 1H21.

Financial Highlights

- **Cash Position:** TCR² ended the first quarter of 2020 with \$140.7 million in cash, cash equivalents, and investments compared to \$158.1 million as of December 31, 2019. Net cash used in operations was \$16.4 million for the first quarter of 2020 compared to \$10.8 million for first quarter of 2019. TCR² projects net cash use of \$60-70 million for 2020.
 - **R&D Expenses:** Research and development expenses were \$12.0 million for the first quarter of 2020 compared to \$7.9 million for the first quarter of 2019. The increase in R&D expenses is primarily related to increase in headcount, activities related to the Phase 1/2 clinical trial of TC-210 and activities related to the Phase 1/2 clinical trial of TC-110.
 - **G&A Expenses:** General and administrative expenses were \$4.3 million for the first quarter of 2020 compared to \$2.9 million for the first quarter of 2019. The increase in general and administrative expenses was primarily due to an increase in personnel costs and costs associated with operations as a public company.
 - **Net Loss:** Net loss was \$15.5 million for the first quarter of 2020 compared to \$9.9 million for the first quarter of 2019, driven predominantly by increased R&D expenses.
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Upcoming Events

TCR² Therapeutics management is scheduled to participate at the following upcoming conference.

- Jefferies Global Healthcare Conference: Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics, and Ian Somaiya, Chief Financial Officer of TCR² Therapeutics, will participate in a fireside chat using a virtual platform on Tuesday, June 2, 2020 at 9:00am ET

About TCR² Therapeutics

TCR² Therapeutics Inc. is a clinical-stage immunotherapy company developing the next generation of novel T cell therapies for patients suffering from cancer. 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 exhibiting lower levels of cytokine release. The Company's lead TRuC-T cell product candidate targeting solid tumors, TC-210, 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.

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 anticipated timing of updates from TCR²'s ongoing Phase 1 portion of the TC-210 clinical trial in mid-2020 and the ongoing Phase 1 portion of the TC-110 clinical trial in 2H20, anticipated clinical production of TRuC-T cells at TCR²'s manufacturing facility in Stevenage, UK, in 2H20, anticipated patient populations for TC-110, anticipated updates on new product candidates, targets, platform enhancements and IND filings, and TCR²'s expectations with respect to its financial resources and the impact that the current COVID-19 pandemic will have on the Company's clinical trials and operations.

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, whether TCR²'s cash resources will be sufficient to fund TCR²'s foreseeable and unforeseeable operating expenses and capital expenditure requirements; the risk that the current COVID-19 pandemic will impact the Company's clinical trials and other 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.

Moreover, except as required by law, neither TCR2 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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TCR² THERAPEUTICS INC.
UNAUDITED CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except share data)

	March 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 31,093	\$ 65,296
Investments	95,023	92,828
Prepaid expenses and other current assets	6,841	5,061
Total current assets	132,957	163,185
Property and equipment, net	5,220	4,926
Investments, non-current	14,540	-
Restricted cash	417	417
Deferred offering costs	170	-
Total assets	\$ 153,304	\$ 168,528
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Accounts payable	\$ 3,179	\$ 2,483
Accrued expenses and other current liabilities	2,950	5,050
Total current liabilities	6,129	7,533
Other liabilities	583	546
Total liabilities	6,712	8,079
Stockholders' equity (deficit)		
Common stock, \$0.0001 par value; 150,000,000 authorized; 24,075,906 and 24,050,936 shares issued; 24,056,469 and 23,981,109 shares outstanding at March 31, 2020 and December 31, 2019, respectively.	2	2
Additional paid-in capital	345,149	342,896
Accumulated other comprehensive income (loss)	(462)	142
Accumulated deficit	(198,097)	(182,591)
Total stockholders' equity (deficit)	146,592	160,449
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	\$ 153,304	\$ 168,528

TCR² THERAPEUTICS INC.
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)

	For the Three Months Ended March 31,	
	2020	2019
Operating expenses		
Research and development	\$ 11,955	\$ 7,889
General and administrative	4,271	2,886
Total operating expenses	16,226	10,775
Loss from operations	(16,226)	(10,775)
Interest income, net	747	872
Loss before income taxes	(15,479)	(9,903)
Income taxes	27	-
Net loss	(15,506)	(9,903)
Accretion of redeemable convertible preferred stock to redemption value	-	(49,900)
Net loss attributable to common stockholders	<u>\$ (15,506)</u>	<u>\$ (59,803)</u>
Per share information		
Net loss per share of common stock, basic and diluted	<u>\$ (0.65)</u>	<u>\$ (4.85)</u>
Weighted average shares outstanding, basic and diluted	24,011,843	12,328,805

TCR² THERAPEUTICS INC.
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS
(amounts in thousands)

	<u>Three months Ended March 31,</u>	
	<u>2020</u>	<u>2019</u>
Operating activities		
Net loss	\$ (15,506)	\$ (9,903)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	306	135
Stock-based compensation expense	2,055	1,141
Accretion on investments	(164)	(131)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,589)	(1,364)
Accounts payable	603	(401)
Accrued expenses and other liabilities	(2,115)	(310)
Cash used in operating activities	<u>(16,410)</u>	<u>(10,833)</u>
Investing activities		
Purchases of equipment	(504)	(188)
Purchase of investments	(47,956)	(86,626)
Proceeds from sale or maturity of investments	30,617	16,819
Cash used in investing activities	<u>(17,843)</u>	<u>(69,995)</u>
Financing activities		
Proceeds from initial public offering, net of issuance costs	-	80,213
Proceeds from the exercise of stock options	185	-
Deferred offering costs	(135)	(654)
Cash provided by financing activities	<u>50</u>	<u>79,559</u>
Net change in cash, cash equivalents, and restricted cash	(34,203)	(1,269)
Cash, cash equivalents, and restricted cash at beginning of year	65,713	47,964
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 31,510</u>	<u>\$ 46,695</u>

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