

**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):
August 8, 2019**

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, Massachusetts 02142**
(Address of principal executive offices, including 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 ☒ x

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 August 8, 2019, TCR² Therapeutics Inc. announced its financial results for the quarter ended June 30, 2019. 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	<u>Press release dated August 8, 2019</u>

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: August 8, 2019

TCR² Therapeutics Inc.

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



TCR² Therapeutics Reports Second Quarter 2019 Financial Results and Provides Corporate Update

- Began dosing of TC-210 in the Phase 1/2 trial for patients with mesothelin-expressing solid tumors and an interim update anticipated in 4Q19/1Q20
- Leading clinical sites participating in the TC-210 trial include Sarah Cannon Research Institute, MD Anderson Cancer Center and the National Cancer Institute
- IND filing for TC-110 in patients with CD19+ non-Hodgkin lymphoma or adult acute lymphoblastic leukemia anticipated in 2H19

CAMBRIDGE, Mass., August 8, 2019 - 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 second quarter ended June 30, 2019 and provided a corporate update.

"In the second quarter of 2019, we made significant progress with our two lead programs TC-210 and TC-110," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. "We began patient dosing in a Phase 1/2 clinical trial with TC-210 and partnered with the National Cancer Institute, an institution integral in the validation of targeting mesothelin, to further understand how our unique TRuC-T cells impact mesothelin-positive solid tumors. Additionally, we accelerated our ability to move programs toward and through the clinic by expanding our leadership team with experts that deepen our core competencies - manufacturing, IND enablement and innovation. We remain in a strong financial position with a cash runway into 2022 and look forward to providing updates on TC-210 as we progress through the clinic."

Recent Developments

- TCR² has begun dosing in its Phase 1/2 clinical trial of TC-210 to treat patients with mesothelin-positive non-small cell lung cancer (NSCLC), ovarian cancer, malignant pleural/peritoneal mesothelioma or cholangiocarcinoma.
- TCR² announced that it entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) to collaborate on the use of TCR²'s proprietary TRuC-T cells as a cancer therapeutic agent against mesothelin in the Company's ongoing Phase 1/2 trial of TC-210.
- TCR² expanded its manufacturing and immuno-oncology expertise by hiring Vice Presidents Nigel Williams, Robert Tighe and Dario Gutierrez, Ph.D. The expansion of the leadership team strengthens the Company's core competencies of manufacturing, IND enablement and innovation as it advances a broad portfolio of next generation TRuC-T cells.
- The United States Patent and Trademark Office issued patents with claims covering TCR²'s T cell receptor (TCR) Fusion Construct T cells (TRuCTM-T cells) that express anti-B-cell maturation antigen (BCMA) and anti-CD19 TCR fusion proteins, including TC-110.

TC-210 Clinical Trial Design

- The Phase 1/2 clinical trial (NCT03907852) is evaluating the safety and efficacy of TC-210, TCR²'s T-cell receptor fusion construct against mesothelin at Sarah Cannon Research Institute, MD Anderson Cancer Center and the NCI. The trial is enrolling patients with mesothelin expressing non-small cell lung cancer (NSCLC), ovarian cancer, cholangiocarcinoma or malignant pleural/peritoneal mesothelioma.
- The Phase 1 portion of the clinical trial utilizes a 3+3 design with four escalating dose levels for TC-210. At each dose level, TC-210 is first administered without lymphodepletion and then following lymphodepleting chemotherapy. The primary objective for the study is patient safety with a key secondary objective to determine the recommended Phase 2 dose (RP2D). In addition to standard measures of safety and efficacy, translational work includes the assessment of TC-210 T cells for expansion, trafficking, persistence and phenotypic changes.

- Under the terms of the CRADA, NCI will conduct translational studies, measuring potential biomarkers in patients treated with TCR² Therapeutics' proprietary mesothelin-specific T cell-based therapy to better understand the pharmacodynamics of TC-210.
- In the Phase 2 portion of the clinical trial, approximately 50 patients are initially planned to receive TC-210 at the RP2D in four distinct cohorts according to their cancer diagnosis: NSCLC, ovarian cancer, malignant pleural/peritoneal mesothelioma and cholangiocarcinoma. Each cohort includes ten patients, except the NSCLC cohort which includes 20 patients with eight patients to receive TC-210 as single agent and 12 to receive TC-210 in combination with a programmed cell death 1 (PD-1) blocking antibody.

Financial Highlights

- **Cash Position:** TCR² ended the second quarter of 2019 with \$180.7 million in cash, cash equivalents, and investments compared to \$123.2 million as of December 31, 2018. Net cash used in operations was \$21.0 million in the first half of 2019 compared to \$7.7 million in the first half of 2018.
- **R&D Expenses:** Research and development expenses were \$8.8 million for the second quarter of 2019 compared to \$5.2 million for the second quarter of 2018. The increase in R&D expenses is primarily related to increase in headcount and activities related to the start of the Phase 1/2 clinical trial of the Company's lead solid tumor product candidate, TC-210.
- **G&A Expenses:** General and administrative expenses were \$3.3 million for the second quarter of 2019 compared to \$1.6 million for the second quarter of 2018. The increase in general and administrative expenses was primarily due to an increase in personnel costs and cost associated with operations as a public company.
- **Net loss:** Net loss was \$11.1 million for the second quarter of 2019 compared to \$6.2 million for the second quarter of 2018, driven predominantly by increased R&D expense in the quarter.

Upcoming Events

TCR² Therapeutics management are scheduled to participate at the following upcoming conferences.

- BTIG Biotechnology Conference 2019: Ian Somaiya, Chief Financial Officer of TCR² Therapeutics, will be available for one-on-one meetings on Monday, August 12, 2019 in New York, NY.
- 2019 Wedbush PacGrow Healthcare Conference: Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics, will present on Tuesday, August 13, 2019 at 8:00am ET in New York, NY.

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, 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. 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 updates from the TC-210 Phase 1/2 trial in 4Q19/1Q20, an anticipated IND filing for TC-110 in 2H19, the Company's ability to advance programs into and through the clinic, and the Company's cash runway into 2022.

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; 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.

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TCR² THERAPEUTICS INC.
UNAUDITED CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except share data)

	June 30, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	\$ 40,980	\$ 47,674
Investments	128,646	75,493
Prepaid expenses and other current assets	6,051	2,326
Total current assets	175,677	125,493
Property and equipment, net	3,172	1,638
Investments, non-current	11,121	—
Restricted cash	290	290
Deferred offering costs	—	2,012
Total assets	\$ 190,260	\$ 129,433
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Accounts payable	\$ 4,044	\$ 2,663
Accrued expenses and other current liabilities	3,116	2,802
Total current liabilities	7,160	5,465
Other liabilities	464	434
Total liabilities	7,624	5,899
Redeemable convertible preferred stock		
Series A preferred stock, \$0.0001 par value; no shares and 45,000,000 authorized, issued, or outstanding at June 30, 2019 and December 31, 2018.	—	72,980
Series B preferred stock, \$0.0001 par value; no shares and 62,500,000 authorized, issued, or outstanding at June 30, 2019 and December 31, 2018.	—	136,250
Total redeemable convertible preferred stock	—	209,230
Stockholders' equity (deficit)		
Preferred stock, \$0.0001 par value. 10,000,000 and no shares authorized, issued or outstanding at June 30, 2019 and December 31, 2018, respectively.	—	—
Common stock, \$0.0001 par value; 150,000,000 and 20,988,730 shares authorized at June 30, 2019 and December 31, 2018, respectively; 23,964,746 and 914,602 shares issued at June 30, 2019 and December 31, 2018, respectively; 23,856,689 and 726,994 shares outstanding at June 30, 2019 and December 31, 2018, respectively.	2	—
Additional paid-in capital	338,380	—
Accumulated other comprehensive income (loss)	212	(106)
Accumulated deficit	(155,958)	(85,590)
Total stockholders' equity (deficit)	182,636	(85,696)
Total liabilities, redeemable preferred stock and stockholders' equity (deficit)	\$ 190,260	\$ 129,433

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development	\$ 8,833	\$ 5,175	\$ 16,722	\$ 8,068
General and administrative	3,307	1,634	6,193	2,854
Total operating expenses	12,140	6,809	22,915	10,922
Loss from operations	(12,140)	(6,809)	(22,915)	(10,922)
Interest income, net	1,077	622	1,949	749
Net loss	(11,063)	(6,187)	(20,966)	(10,173)
Accretion of redeemable convertible preferred stock to redemption value	—	(11,145)	(49,900)	(21,978)
Net loss attributable to common stockholders	<u>\$ (11,063)</u>	<u>\$ (17,332)</u>	<u>\$ (70,866)</u>	<u>\$ (32,151)</u>
Per share information				
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.46)</u>	<u>\$ (27.97)</u>	<u>\$ (3.91)</u>	<u>\$ (56.75)</u>
Weighted-average shares outstanding, basic and diluted	23,818,003	619,749	18,105,142	566,513

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

	Six Months Ended June 30,	
	2019	2018
Operating activities:		
Net loss	\$ (20,966)	(10,173)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	300	188
Stock-based compensation expense	2,585	633
Loss on fixed asset disposal	—	2
Accretion on investments	(252)	(76)
Changes in operating assets and liabilities:		
Interest receivable on investments	(325)	(78)
Prepaid expenses and other current assets	(3,158)	153
Accounts payable	180	1,165
Accrued expenses and other liabilities	646	493
Cash used in operating activities	(20,990)	(7,693)
Investing activities:		
Purchase of investments	(106,566)	(32,343)
Proceeds from maturity of investments	42,619	5,530
Purchases of equipment	(941)	(772)
Cash used in investing activities	(64,888)	(27,585)
Financing activities:		
Proceeds from the sale of Series B preferred stock	—	125,000
Proceeds from initial public offering, net of issuance costs	80,213	—
Proceeds from the exercise of stock options	18	219
Deferred offering costs	(1,047)	(57)
Payment of issuance costs	—	(150)
Cash provided by financing activities	79,184	125,012
Net change in cash, cash equivalents, and restricted cash	(6,694)	89,734
Cash, cash equivalents, and restricted cash at beginning of year	47,964	20,101
Cash, cash equivalents, and restricted cash at end of period	\$ 41,270	\$ 109,835

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