## 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 12, 2020

#### TCR2 THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware

001-38811

47-4152751

(State or other jurisdiction of incorporation)

(Commission File Number)

(I.R.S Employer Identification No.)

100 Binney Street

Suite 710

Cambridge MA

02142

(Zip Code)

(Address of Principal Executive Offices)

(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 Nasdag 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 ⊠

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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 12, 2020, TCR<sup>2</sup> Therapeutics Inc. announced its financial results for the quarter ended June 30, 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

Exhibit No.	Description
99.1	Press release dated August 12, 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: August 12, 2020 TCR<sup>2</sup> Therapeutics Inc.

By: <u>/s/ Mayur (Ian) Somaiya</u>

Mayur (Ian) Somaiya Chief Financial Officer



### TCR<sup>2</sup> Therapeutics Reports Second Quarter 2020 Financial Results and Provides Corporate Update

- TC-210 patient with partial response confirmed by independent central review and tumor regression improved further from 42% to 75%
- Began dosing of TC-110 in the Phase 1/2 trial for patients with CD19+ NHL or adult ALL
- Addition of MD Anderson Cancer Center, a leading clinical site, to the TC-110 Phase 1/2 clinical trial
- Raised gross proceeds of \$142.6 million in a secondary offering in July; extended cash runway into 2023

**CAMBRIDGE, Mass.,** August 12, 2020 - TCR<sup>2</sup> Therapeutics Inc. (Nasdaq: TCRR), a clinical-stage immunotherapy company with a pipeline of novel T cell therapies for patients suffering from cancer, today announced financial results for the second quarter ended June 30, 2020 and provided a corporate update.

"The second quarter was incredibly strong for the Company as we continued to deliver significant progress in our clinical trials of TC-210 and TC-110 despite the pandemic. We are particularly pleased to update that, following the earlier announcement of five of our first five cancer patients showing tumor regression with TC-210, one patient is now a confirmed partial response based on independent central review and experienced further tumor regression from 42% to 75%," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR2 Therapeutics. "The initial data from TC-210 provide meaningful readthrough for our TRuC-T cell platform and we believe our robust preclinical pipeline supports our next phase of growth as we build a leading cell therapy company treating solid tumors. The strengthening of our balance sheet through our recent financing puts us in an excellent position to execute on our objectives and provide further clinical and scientific updates in 2020."

#### **Recent Developments**

- TCR2 announced positive interim data from the first five patients treated in the Phase 1 portion of the TC-210 Phase 1/2 clinical trial for mesothelin-expressing solid tumors. All five patients showed tumor regression including two with RECIST partial response, one of which is now confirmed and two patients with stable disease through six months. Translational data further demonstrated TRuC-T cell expansion and activation. A manageable toxicity profile was observed with only one patient exhibiting TC-210-related non-hematologic grade >2 toxicity and no evidence of neurotoxicity or on-target, off-tumor toxicity.
- TCR2 highlighted preclinical data at the American Association for Cancer Research (AACR) Virtual Annual Meeting II of the
  Company's proprietary T Cell Receptor Fusion Construct (TRuC®) T cells that co-express a PD-1:CD28 switch receptor, which acts
  as a cell-intrinsic mechanism to overcome PD-L1/PD-L2 mediated immunosuppression. Upon repeated antigen stimulation, coexpression of the switch receptor in mesothelin-targeting TC-210 T cells enhanced TCR downstream signaling, prevented PD-L1mediatied functional T-cell inhibition, significantly increased proliferation and augmented the production of growth and effector
  cytokines.
- TCR<sup>2</sup> announced the expansion of its leadership team with key business development and regulatory affairs cell therapy experts
  with the appointments of Gregg McConnell as Head of Business Development and Viera Muzithras as Vice President of Regulatory
  Affairs.

#### **Anticipated Milestones**

- TCR2 anticipates an interim update from the Phase 1 portion of the TC-210 Phase 1/2 clinical trial for patients with mesothelinexpressing solid tumors in 2H20.
- TCR<sup>2</sup> 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.
- TCR<sup>2</sup> anticipates certification of its manufacturing facility in Stevenage, UK, in 2H20.
- TCR2 anticipates an IND filing for a third TRuC-T cell program in 2021.

#### **Financial Highlights**

- Cash Position: TCR<sup>2</sup> ended the second quarter of 2020 with \$124.8 million in cash, cash equivalents, and investments compared to \$158.1 million as of December 31, 2019. As a result of the recent equity offering, TCR<sup>2</sup> raised an additional \$134.6 million. Net cash used in operations was \$16.0 million for the second quarter of 2020 compared to \$10.2 million for second quarter of 2019. TCR<sup>2</sup> continues to project net cash use of \$60-70 million for 2020.
- **R&D Expenses**: Research and development expenses were \$12.9 million for the second quarter of 2020 compared to \$8.8 million for the second 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 \$3.8 million for the second quarter of 2020 compared to \$3.3 million for the second 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 \$16.2 million for the second quarter of 2020 compared to \$11.1 million for the second quarter of 2019, driven predominantly by increased R&D expenses.

#### **Upcoming Events**

TCR<sup>2</sup> Therapeutics management is scheduled to participate at the following upcoming conferences.

- 2020 Wedbush PacGrow Healthcare Virtual Conference: Ian Somaiya, Chief Financial Officer of TCR<sup>2</sup> Therapeutics, will provide a company update using a virtual platform on Wednesday, August 12, 2020 at 10:55am ET
- Cantor Fitzgerald Virtual Global Healthcare Conference: Garry Menzel, Ph.D., President and Chief Executive Officer of TCR<sup>2</sup>
  Therapeutics, and Ian Somaiya, Chief Financial Officer of TCR<sup>2</sup> Therapeutics, will provide a company update using a virtual platform on Wednesday, September 16, 2020 at 8:40am ET

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

TCR<sup>2</sup> Therapeutics Inc. is a clinical-stage immunotherapy 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®-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, 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 the therapeutic potential of TC-210, future 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

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)

	Ju	June 30, 2020		December 31, 2019		
Assets			_			
Current assets						
Cash and cash equivalents	\$	49,695	\$	65,296		
Investments		75,118		92,828		
Prepaid expenses and other current assets		8,964		5,061		
Total current assets		133,777		163,185		
Property and equipment, net		5,957		4,926		
Restricted cash		417		417		
Deferred offering costs		231		-		
Total assets	\$	140,382	\$	168,528		
Liabilities and stockholders' equity (deficit)						
Accounts payable	\$	2,987	\$	2,483		
Accrued expenses and other current liabilities		3,373		5,050		
Total current liabilities		6,360		7,533		
Other liabilities		609		546		
Total liabilities		6,969		8,079		
Stockholders' equity (deficit)						
Common stock, \$0.0001 par value; 150,000,000 shares authorized; 24,139,510 and 24,050,936 shares issued; 24,104,595 and 23,981,109 shares outstanding at June 30, 2020 and December 31, 2019,						
respectively.		2		2		
Additional paid-in capital		347,351		342,896		
Accumulated other comprehensive income (loss)		402		142		
Accumulated deficit		(214,342)		(182,591)		
Total stockholders' equity (deficit)		133,413		160,449		
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	\$	140,382	\$	168,528		

# 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,			
		2020	2019		2020		2019	
Operating expenses	· ·	_					_	
Research and development	\$	12,907	\$ 8,833	\$	24,862	\$	16,722	
General and administrative		3,809	3,307		8,080		6,193	
Total operating expenses		16,716	12,140		32,942		22,915	
Loss from operations		(16,716)	(12,140)		(32,942)		(22,915)	
Interest income, net		499	1,077		1,246		1,949	
Loss before income taxes		(16,217)	(11,063)		(31,696)		(20,966)	
Income taxes		28		_	55		-	
Net loss		(16,245)	(11,063)		(31,751)		(20,966)	
							(	
Accretion of redeemable convertible preferred stock to redemption value		<u> </u>	<del>-</del>		<u> </u>	_	(49,900)	
Net loss attributable to common stockholders	\$	(16,245)	\$ (11,063)	\$	(31,751)	\$	(70,866)	
Per share information								
Net loss per share of common stock, basic and diluted	\$	(0.67)	\$ (0.46)	\$	(1.32)	\$	(3.91)	
	· ·							
Weighted average shares outstanding, basic and diluted		24,075,984	23,818,003		24,043,913		18,105,142	

### TCR2 THERAPEUTICS INC. UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)

	Six Months Ended June 30,				
	 2020		2019		
Operating activities					
Net loss	\$ (31,751)	\$	(20,966)		
Adjustments to reconcile net loss to cash used in operating activities:					
Depreciation and amortization	673		300		
Stock-based compensation expense	4,119		2,585		
Changes in operating assets and liabilities:					
Prepaid expenses and other current assets	(3,904)		(3,735)		
Accounts payable	29		180		
Accrued expenses and other liabilities	 (1,587)		646		
Cash used in operating activities	 (32,421)		(20,990)		
Investing activities					
Purchases of equipment	(1,229)		(941)		
Purchases of investments	(63,005)		(106,566)		
Proceeds from sale or maturity of investments	 80,975		42,619		
Cash provided by (used in) investing activities	 16,741		(64,888)		
Financing activities					
Proceeds from initial public offering, net of issuance costs	-		80,213		
Proceeds from the exercise of stock options	310		18		
Deferred offering costs	(231)		(1,047)		
Cash provided by financing activities	 79		79,184		
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Net change in cash, cash equivalents, and restricted cash	(15,601)		(6,694)		
Cash, cash equivalents, and restricted cash at beginning of year	65,713		47,964		
Cash, cash equivalents, and restricted cash at end of period	\$ 50,112	\$	41,270		