

**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 5, 2021**

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

02142

(Address of Principal Executive Offices)

(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 August 5, 2021, TCR² Therapeutics Inc. announced its financial results for the fiscal quarter ended June 30, 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

Exhibit No.	Description
99.1	Press release dated August 5, 2021
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 5, 2021

TCR² Therapeutics Inc.

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



TCR² Therapeutics Reports Second Quarter 2021 Financial Results and Provides Corporate Update

- New clinical data from gavo-cel Phase 1 trial to be presented at European Society of Medical Oncology (ESMO)
- Remain on track to identify recommended Phase 2 dose (RP2D) for gavo-cel in 2021
- TCR² to host virtual R&D Day on October 20, 2021 to highlight emerging pipeline

CAMBRIDGE, Mass., August 5, 2021 - TCR² 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 second quarter ended June 30, 2021 and provided a corporate update.

"As we enter the second half of the year, we are approaching the conclusion of the Phase 1 portion of our gavo-cel clinical trial and selection of an RP2D. We look forward to presenting safety, efficacy and translational data from at least 17 patients, up to dose level 5, in an oral presentation at the European Society of Medical Oncology Congress on September 17," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. "We believe that gavo-cel has the potential to significantly improve the standard of care for patients with treatment refractory mesothelin-expressing solid tumors. We are focused on identifying the RP2D before the end of 2021 to advance this program into Phase 2 where we can more definitively evaluate efficacy, including retreatment with gavo-cel and combinations with checkpoint inhibitors. We also remain committed to advancing our broad emerging pipeline, including new enhancements, allogeneic TRuC-T cells and new targets and look forward to showcasing these programs at our upcoming virtual R&D Day."

Recent Developments

Gavo-cel:

- TCR² announced today the Company plans to present new clinical data from the dose escalation portion of the Phase 1/2 clinical trial of gavo-cel in patients with treatment refractory mesothelin-expressing solid tumors as part of an oral presentation on September 17 at 14:20 CEST (8:20am EST) at the European Society for Medical Oncology (ESMO) Congress 2021 being held in-person from September 16-21, 2021. The presentation will include long-term follow-up from initial and new patients from the Phase 1 dose escalation, with data from additional non-mesothelioma patients, and will focus on safety, efficacy and translational data at dose levels 3 (1×10^8 cells/m² with lymphodepletion), 4 (5×10^8 cells/m² without lymphodepletion) and 5 (5×10^8 cells/m² with lymphodepletion).

Corporate:

- TCR² announced today that it will host a virtual R&D Day on Wednesday, October 20, 2021 to showcase the broad emerging pipeline focusing on its enhancements, allogeneic strategies and new targets.
- TCR² announced the appointment of Peter Olagunju as its first Chief Technical Officer where he will oversee process development, manufacturing, quality control and technical operations for the Company's TRuC-T cell programs and emerging pipeline. Previously, Mr. Olagunju was Senior Vice President of Technical Operations at FerGene, Inc. Before that, Mr. Olagunju was Vice President of Global Patient Operations at bluebird bio, Inc., where he held several roles of increasing responsibility and was the program lead and functional head of manufacturing supporting the European approval for ZYNTEGLO®, a transformational gene therapy for Transfusion dependent Thalassemia.

Anticipated Milestones

- TCR² to highlight interim progress from the Phase 1 portion of the gavo-cel Phase 1/2 clinical trial for patients with mesothelin-expressing solid tumors in an abstract at the 2021 World Conference on Lung Cancer.
- TCR² to highlight additional safety, efficacy and translational data from all patients receiving therapy up to dose level 5 (second and third gavo-cel doses) in the Phase 1 portion of the gavo-cel Phase 1/2 clinical trial focused on mesothelin-expressing solid tumors in an oral presentation at the ESMO Congress 2021.
- TCR² 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.
- TCR² 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.
- TCR² plans to select a development candidate for its allogeneic program in the second half of 2021.
- TCR² to present preclinical data on its IL-15 enhancements program in the fourth quarter of 2021.
- TCR² to host virtual R&D Day focused on the broad emerging pipeline on October 20, 2021.
- TCR² 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:** TCR² ended the second quarter of 2021 with \$317.3 million in cash, cash equivalents, and investments compared to \$228.0 million as of December 31, 2020. Net cash used in operations was \$15.0 million for the second quarter of 2021 compared to \$16.0 million for the second quarter of 2020. TCR² 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 \$18.6 million for the second quarter of 2021 compared to \$12.9 million for the second quarter of 2020. The increase in R&D expenses was primarily due to an increase in headcount, additional lab facilities, and manufacturing facilities.
- **G&A Expenses:** General and administrative expenses were \$5.7 million for the second quarter of 2021 compared to \$3.8 million for the second quarter of 2020. The increase in general and administrative expenses was primarily due to an increase in personnel costs and external professional fees.
- **Net Loss:** Net loss was \$24.3 million for the second quarter of 2021 compared to \$16.2 million for the second quarter of 2020.

Adoption of New Lease Standard

During the second quarter of 2021, TCR² adopted the new lease standard ASC 842 effective January 1, 2021. The lease standard requires companies to record right-of-use assets and lease liabilities for all leases. With the adoption of the new lease standard, the Company removed its facility in Rockville, MD as an asset under a built-to-suit lease in the amount of \$41 million and removed the associated liabilities of \$37 million. As of June 30, 2021, the Company's right-of-use assets under operating leases, including the Rockville facility, were \$30.6 million and operating lease liabilities were \$27.6 million.

Upcoming Events

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

- 2021 Wedbush PacGrow Healthcare Conference: Robert Hofmeister, Ph.D., Chief Scientific Officer of TCR² Therapeutics, will participate in a panel using a virtual platform on Tuesday, August 10, 2021 at 9:45am ET

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 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 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.

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 of updates for the gavo-cel and TC-110 clinical trials, expectations with respect to timing of our IND submission for TC-510, expectations regarding preclinical data for our emerging pipeline and enhancements, timing for the certification of operation of our manufacturing facilities in Stevenage, UK and Rockville, MD, increased manufacturing capacity and technical capabilities, including through 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.

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)

	June 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 248,793	\$ 94,155
Investments	68,553	133,831
Prepaid expenses and other current assets	7,882	7,552
Total current assets	325,228	235,538
Property and equipment, net		
	10,722	10,013
Right-of-use assets, operating leases	30,559	-
Restricted cash	1,141	583
Other assets, non-current	490	61
Total assets	\$ 368,140	\$ 246,195
Liabilities and stockholders' equity		
Liabilities		
Accounts payable	\$ 4,819	\$ 2,448
Accrued expenses and other current liabilities	6,533	6,392
Operating lease liabilities	3,594	-
Total current liabilities	14,946	8,840
Operating lease liabilities, non-current		
	24,046	-
Other liabilities	257	807
Total liabilities	39,249	9,647
Stockholders' equity		
Common stock, \$0.0001 par value; 150,000,000 shares authorized; 38,181,331 and 33,516,795 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively.	4	3
Additional paid-in capital	624,445	486,197
Accumulated other comprehensive income	(19)	63
Accumulated deficit	(295,539)	(249,715)
Total stockholders' equity	328,891	236,548
Total liabilities and stockholders' equity	\$ 368,140	\$ 246,195

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,	
	2021	2020	2021	2020
Operating expenses				
Research and development	\$ 18,627	\$ 12,907	\$ 34,551	\$ 24,862
General and administrative	5,666	3,809	11,334	8,080
Total operating expenses	24,293	16,716	45,885	32,942
Loss from operations	(24,293)	(16,716)	(45,885)	(32,942)
Interest income, net	32	499	148	1,246
Loss before income tax expense	(24,261)	(16,217)	(45,737)	(31,696)
Income tax expense	51	28	87	55
Net loss	<u>\$ (24,312)</u>	<u>\$ (16,245)</u>	<u>\$ (45,824)</u>	<u>\$ (31,751)</u>
Per share information				
Net loss per share of common stock, basic and diluted	<u>\$ (0.64)</u>	<u>\$ (0.67)</u>	<u>\$ (1.22)</u>	<u>\$ (1.32)</u>
Weighted average shares outstanding, basic and diluted	38,176,025	24,075,984	37,622,390	24,043,913

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

	Six Months Ended June 30,	
	2021	2020
Operating activities		
Net loss	\$ (45,824)	\$ (31,751)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,203	673
Stock-based compensation expense	6,339	4,119
Accretion on investments	417	(392)
Deferred tax liabilities	63	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(490)	(3,512)
Operating leases, net	(3,415)	-
Accounts payable	2,587	29
Accrued expenses and other liabilities	178	(1,587)
Cash used in operating activities	(38,942)	(32,421)
Investing activities		
Purchases of equipment	(2,184)	(1,229)
Software development costs	(128)	-
Purchases of investments	(40,732)	(63,005)
Proceeds from sale or maturity of investments	105,518	80,975
Cash provided by investing activities	62,474	16,741
Financing activities		
Proceeds from public offering of common stock, net of issuance costs	131,330	-
Proceeds from the exercise of stock options	580	310
Payment of deferred offering costs	(246)	(231)
Cash provided by financing activities	131,664	79
Net change in cash, cash equivalents, and restricted cash	155,196	(15,601)
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>\$ 249,934</u>	<u>\$ 50,112</u>
Supplemental disclosure of noncash activities		
Property and equipment additions in accounts payable	\$ 395	\$ 745
Right-of-use assets obtained in exchange for operating lease liabilities	21,241	-
Operating cash flows used in operating leases	6,379	-

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