

**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, 2022**

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 August 8, 2022, TCR² Therapeutics Inc. announced its financial results for the fiscal quarter ended June 30, 2022. 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 8, 2022
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 8, 2022

TCR² Therapeutics Inc.

By: /s/ Eric Sullivan
Eric Sullivan
Chief Financial Officer



TCR² Therapeutics Reports Second Quarter 2022 Financial Results and Provides Corporate Update

- gavo-cel Phase 1 trial dataset anticipated in September 2022
- Initial TC-510 Phase 1 data anticipated in 2H 2022

- Expansion of manufacturing capacity and commencement of gavo-cel clinical trial material production at ElevateBio BaseCamp

CAMBRIDGE, Mass., August 8, 2022 - TCR² Therapeutics Inc. (Nasdaq: TCRR), a clinical-stage cell therapy company with a pipeline of novel T cell therapies for cancer patients suffering from solid tumors, today announced financial results for the second quarter ended June 30, 2022 and provided a corporate update.

"TCR² made significant strides this quarter in preparation for our upcoming gavo-cel Phase 1 and TC-510 data expected in the second half of 2022. As part of our commitment to deliver a meaningfully interpretable dataset, we plan to present our gavo-cel Phase 1 trial data on at least 30 patients in September in order to collect additional scans on patients evaluable for efficacy," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. "We also continue to expect to present initial safety, efficacy and translational data from our TC-510 Phase 1 clinical trial before the end of 2022. In connection with progressing our two mesothelin-focused clinical trials, we have activated additional clinical sites and expanded our manufacturing capacity through ElevateBio BaseCamp. This will allow us to further accelerate the pace at which we can deliver our unique cell therapy to benefit patients suffering from solid tumors."

Recent Developments

TC-510:

- TCR² initiated the Phase 1 dose escalation portion of the Phase 1/2 clinical trial of TC-510, its first enhanced mesothelin-targeted TRuC-T cell that co-expresses a PD-1:CD28 chimeric switch receptor. Enrollment is ongoing and the Company expects to report on initial safety, efficacy and translational data from at least one of the Phase 1 dose escalation cohorts of the Phase 1/2 clinical trial in the second half of 2022.

Corporate:

- TCR² announced the appointment of industry and finance veteran Eric Sullivan as Chief Financial Officer where he will be responsible for leading all aspects of financial management and capital market strategy as well as overseeing investor relations and select business operations.

Manufacturing:

- TCR² announced today the commencement of clinical trial material production at ElevateBio BaseCamp in anticipation of increased demand from the Phase 2 expansion trial of gavo-cel.

Anticipated Milestones

Gavo-cel:

- Present the expanded Phase 1 dataset for gavo-cel in September 2022.
- Provide an update from the Phase 2 portion of the ongoing gavo-cel Phase 1/2 clinical trial in the second half of 2022.

TC-510:

- Report initial safety, efficacy and translational data from at least one of the Phase 1 dose escalation cohorts of the TC-510 Phase 1/2 clinical trial in the second half of 2022.

Pipeline:

- Initiate IND-enabling studies for TC-520, an enhanced CD70 targeting TRuC-T cell program, in 2022.

Financial Highlights

- **Cash Position:** TCR² ended the second quarter of 2022 with \$206.2 million in cash, cash equivalents, and investments compared to \$265.6 million as of December 31, 2021. Net cash used in operations was \$19.5 million for the second quarter of 2022 compared to \$15.0 million for the second quarter of 2021. TCR² projects net cash use of \$115-125 million for 2022. We expect cash on hand to support operations into 2024.
- **R&D Expenses:** Research and development expenses were \$25.8 million for the second quarter of 2022 compared to \$18.6 million for the second quarter of 2021. The increase in R&D expenses was primarily due to an increase in contract manufacturing costs and clinical trial expenses associated with patient treatment and headcount.
- **G&A Expenses:** General and administrative expenses were \$6.0 million for the second quarter of 2022 compared to \$5.7 million for the second quarter of 2021. The increase in general and administrative expenses was due to an increase in personnel costs and other professional fees.
- **Net Loss:** Net loss was \$31.6 million for the second quarter of 2022 compared to \$24.3 million for the second quarter of 2021.

Upcoming Events

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

- Wedbush PacGrow Healthcare Conference: Management will participate in investor one-on-one meetings on August 10, 2022

About TCR² Therapeutics

TCR² Therapeutics Inc. is a clinical-stage cell therapy company developing a pipeline of novel T cell therapies for cancer patients suffering from solid tumors. The company is focused on the discovery and development of product candidates against novel and complex targets utilizing its proprietary T cell receptor (TCR) Fusion Construct T cells (TRuC[®]-T cells). The TRuC platform is designed to specifically recognize and kill cancer cells by harnessing signaling from the entire TCR, independent of human leukocyte antigens (HLA). For more information about TCR², please visit www.tcr2.com.

About gavo-cel

Gavo-cel is a mesothelin-targeted TRuC-T cell. The ongoing gavo-cel Phase 1/2 clinical trial is evaluating the safety and efficacy of gavo-cel in patients with mesothelin-expressing malignant pleural/peritoneal mesothelioma (MPM), ovarian cancer, non-small cell lung cancer (NSCLC) and cholangiocarcinoma.

About TC-510

TC-510 is a mesothelin-targeted TRuC-T cell that co-expresses a PD-1:CD28 chimeric switch receptor to provide a local costimulatory signal by engaging with PD-L1 expressed in the hostile tumor microenvironment and converting the negative inhibitory signal into a positive costimulatory signal. The TC-510 Phase 1/2 clinical trial is evaluating the safety and efficacy of TC-510 in patients with mesothelin-expressing MPM, ovarian cancer, pancreatic cancer, colorectal cancer and triple negative breast cancer.

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, TC-510 and the Company's other product candidates, expected progress and timing of updates for the gavo-cel and TC-510 clinical trials, expectations regarding clinical data for gavo-cel and TC-510 and the timing of an IND submission for TC-520, expectations with respect to manufacturing capacity and technical capabilities, including through the Company's manufacturing partnership with ElevateBio, LLC, expectations with respect to clinical trial demand, future IND-enabling studies and filings, future clinical development plans, expected cash use in 2022 and cash runway into 2024, expectations regarding 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 manufacturing capacity; 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, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 44,211	\$ 222,564
Investments	162,027	43,029
Prepaid expenses and other current assets	9,592	10,534
Total current assets	215,830	276,127
Property and equipment, net		
Property and equipment, net	27,712	17,075
Right-of-use assets, operating leases	62,293	28,283
Restricted cash	1,152	1,156
Other assets, non-current	1,057	730
Total assets	\$ 308,044	\$ 323,371
Liabilities and stockholders' equity		
Liabilities		
Accounts payable	\$ 5,470	\$ 2,144
Accrued expenses and other current liabilities	12,528	13,094
Operating lease liabilities	20,574	3,367
Total current liabilities	38,572	18,605
Operating lease liabilities, non-current		
Operating lease liabilities, non-current	43,209	22,996
Other liabilities	-	293
Total liabilities	81,781	41,894
Stockholders' equity		
Common stock, \$0.0001 par value; 150,000,000 shares authorized; 38,598,916 and 38,496,484 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively.	4	4
Additional paid-in capital	637,175	631,008
Accumulated other comprehensive income (loss)	(671)	(13)
Accumulated deficit	(410,245)	(349,522)
Total stockholders' equity	226,263	281,477
Total liabilities and stockholders' equity	\$ 308,044	\$ 323,371

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,	
	2022	2021	2022	2021
Operating expenses				
Research and development	\$ 25,767	\$ 18,627	\$ 48,650	\$ 34,551
General and administrative	6,004	5,666	12,324	11,334
Total operating expenses	31,771	24,293	60,974	45,885
Loss from operations	(31,771)	(24,293)	(60,974)	(45,885)
Interest income, net	298	32	415	148
Loss before income tax expense	(31,473)	(24,261)	(60,559)	(45,737)
Income tax expense	128	51	164	87
Net loss	<u>\$ (31,601)</u>	<u>\$ (24,312)</u>	<u>\$ (60,723)</u>	<u>\$ (45,824)</u>
Per share information				
Net loss per share of common stock, basic and diluted	<u>\$ (0.82)</u>	<u>\$ (0.64)</u>	<u>\$ (1.58)</u>	<u>\$ (1.22)</u>
Weighted average shares outstanding, basic and diluted	38,566,954	38,176,025	38,540,178	37,622,390

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

	Six Months Ended June 30,	
	2022	2021
Operating activities		
Net loss	\$ (60,723)	\$ (45,824)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,410	1,203
Stock-based compensation expense	6,024	6,339
(Accretion) / Amortization on investments	(140)	417
Deferred tax liabilities	(293)	63
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,119	(490)
Operating leases, net	3,410	(3,415)
Accounts payable	(881)	2,587
Accrued expenses and other liabilities	(591)	178
Cash used in operating activities	<u>(50,665)</u>	<u>(38,942)</u>
Investing activities		
Purchases of equipment	(7,893)	(2,184)
Software development costs	(295)	(128)
Purchases of investments	(186,006)	(40,732)
Proceeds from sale or maturity of investments	66,490	105,518
Cash provided by (used in) investing activities	<u>(127,704)</u>	<u>62,474</u>
Financing activities		
Proceeds from public offering of common stock, net of issuance costs	-	131,330
Proceeds from the exercise of stock options	143	580
Payment of deferred offering costs	(131)	(246)
Cash provided by financing activities	<u>12</u>	<u>131,664</u>
Net change in cash, cash equivalents, and restricted cash	(178,357)	155,196
Cash, cash equivalents, and restricted cash at beginning of year	<u>223,720</u>	<u>94,738</u>
Cash, cash equivalents, and restricted cash at end of period	<u><u>\$ 45,363</u></u>	<u><u>\$ 249,934</u></u>

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