

**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):
November 10, 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 November 10, 2021, TCR² Therapeutics Inc. announced its financial results for the fiscal quarter ended September 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 November 10, 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: November 10, 2021

TCR² Therapeutics Inc.

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



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

CAMBRIDGE, Mass., November 10, 2021 - 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 third quarter ended September 30, 2021 and provided a corporate update.

“Over the last few months, we continue to treat cancer patients in our ongoing gavo-cel Phase 1 clinical trial and have observed meaningful clinical benefit in three different treatment-refractory solid tumor indications,” said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. “As we prepare for the phase 2 trial to be launched in early 2022, we are expanding our US manufacturing footprint and successfully negotiated a clinical trial collaboration agreement with Bristol Myers Squibb, where we will have the opportunity to evaluate the efficacy and duration of gavo-cel in combination with *Opdivo* and *Yervoy*. We anticipate selecting the RP2D before year end and look forward to providing an update on gavo-cel in 1Q22 following review by the US Food and Drug Administration.”

Recent Developments

Gavo-cel:

- TCR² announced positive interim data from the first 17 patients treated in the Phase 1 portion of the gavo-cel Phase 1/2 clinical trial for mesothelin-expressing solid tumors. 15 of the 16 patients evaluable for efficacy experienced regression of their target lesions including 6 patients that achieved a partial response (PR) by target lesion assessment, 4 of whom met criteria for a PR according to RECIST 1.1 criteria. The maximum tolerated dose (MTD) was declared $5 \times 10^8/\text{m}^2$ after lymphodepletion.
- Following identification of the MTD, TCR² announced the completion of the 3-patient cohort at the new dose level 3.5A ($3 \times 10^8/\text{m}^2$ following lymphodepletion) using a split dosing approach. Two patients were evaluable for safety. In both cases, gavo-cel was well-tolerated with no patients experiencing Grade ≥ 3 cytokine release syndrome (CRS).
- TCR² announced a clinical trial collaboration agreement with Bristol Myers Squibb (NYSE: BMY) to evaluate gavo-cel in combination with *Opdivo*[®] (nivolumab) and *Yervoy*[®] (ipilimumab) in its planned Phase 2 clinical trial in treatment refractory mesothelin-expressing solid tumors.

Corporate:

- TCR² announced at its virtual R&D Day on October 20, 2021, its pipeline prioritization of solid tumors and highlighted programs from its emerging TRuC pipeline including TC-510, its first TRuC-T cell enhanced with a PD1xCD28 switch receptor; TC-520, its lead candidate targeting CD70 expressing an IL-15 enhancement; allogeneic TRuC-T cells; and TRuC Tregs, the first utilization of the TRuC platform in the autoimmune setting.
- TCR² announced the expansion of its manufacturing capacity by exercising an option on a second clean room at ElevateBio BaseCamp which adds to the buildout of clinical and commercial supply currently underway at its Rockville, MD facility. In connection with this expansion, TCR² proposes to cease manufacturing activities at the Cell and Gene Therapy Catapult (CGT Catapult) in Stevenage, UK.

Anticipated Milestones

- TCR² anticipates the identification of the recommended Phase 2 dose (RP2D) in 4Q21.
- TCR² plans to file an IND for TC-510, the first enhanced TRuC-T cell (targeting mesothelin with a PD1xCD28 switch), in the first quarter of 2022.
- TCR² anticipates initiation of IND-enabling studies for TC-520, an enhanced CD70 targeting TRuC-T cell program in 2022.
- TCR² plans to select a lead candidate for its allogeneic program in 2022.
- TCR² anticipates production of clinical trial material from ElevateBio BaseCamp in anticipation of demand from the Phase 2 expansion trial of gavo-cel in 2022.

Financial Highlights

- **Cash Position:** TCR² ended the third quarter of 2021 with \$295.7 million in cash, cash equivalents, and investments compared to \$228.0 million as of December 31, 2020. Net cash used in operations was \$19.4 million for the third quarter of 2021 compared to \$10.8 million for the third quarter of 2020. TCR² projects net cash use of \$100-105 million for 2021, the lower end of the range previously provided. We expect cash on hand to support operations through 2023.
- **R&D Expenses:** Research and development expenses were \$20.3 million for the third quarter of 2021 compared to \$12.8 million for the third 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 \$6.0 million for the third quarter of 2021 compared to \$4.4 million for the third quarter of 2020. The increase in general and administrative expenses was primarily due to an increase in personnel costs.
- **Net Loss:** Net loss was \$26.2 million for the third quarter of 2021 compared to \$16.9 million for the third quarter of 2020.

Upcoming Events

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

- Jefferies London Healthcare Conference: Garry Menzel, President and Chief Executive Officer of TCR² Therapeutics, will present an update on Company progress on Tuesday, November 16, 2021 at 12:20pm GMT (7:20am ET)
- Piper Sandler 33rd Annual Virtual Healthcare Conference: management will participate in a fireside chat using a virtual platform on Monday, November 22, 2021 at 10:00am ET

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.

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 and the Company's other product candidates, 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.

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

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 262,497	\$ 94,155
Investments	33,244	133,831
Prepaid expenses and other current assets	7,478	7,552
Total current assets	303,219	235,538
Property and equipment, net		
	12,252	10,013
Right-of-use assets, operating leases	29,432	-
Restricted cash	1,155	583
Other assets, non-current	666	61
Total assets	\$ 346,724	\$ 246,195
Liabilities and stockholders' equity		
Liabilities		
Accounts payable	\$ 4,384	\$ 2,448
Accrued expenses and other current liabilities	8,654	6,392
Operating lease liabilities	3,482	-
Total current liabilities	16,520	8,840
Operating lease liabilities, non-current		
	23,635	-
Other liabilities	299	807
Total liabilities	40,454	9,647
Stockholders' equity		
Common stock, \$0.0001 par value; 150,000,000 shares authorized; 38,220,444 and 33,516,795 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively.	4	3
Additional paid-in capital	628,064	486,197
Accumulated other comprehensive income (loss)	(15)	63
Accumulated deficit	(321,783)	(249,715)
Total stockholders' equity	306,270	236,548
Total liabilities and stockholders' equity	\$ 346,724	\$ 246,195

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses				
Research and development	\$ 20,277	\$ 12,820	\$ 54,828	\$ 37,682
General and administrative	5,963	4,371	17,297	12,451
Total operating expenses	26,240	17,191	72,125	50,133
Loss from operations	(26,240)	(17,191)	(72,125)	(50,133)
Interest income, net	38	300	186	1,546
Loss before income tax expense	(26,202)	(16,891)	(71,939)	(48,587)
Income tax expense	42	31	129	86
Net loss	<u>\$ (26,244)</u>	<u>\$ (16,922)</u>	<u>\$ (72,068)</u>	<u>\$ (48,673)</u>
Per share information				
Net loss per share of common stock, basic and diluted	<u>\$ (0.69)</u>	<u>\$ (0.56)</u>	<u>\$ (1.91)</u>	<u>\$ (1.86)</u>
Weighted average shares outstanding, basic and diluted	38,197,929	30,340,355	37,816,345	26,158,040

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

	Nine Months Ended September 30,	
	2021	2020
Operating activities		
Net loss	\$ (72,068)	\$ (48,673)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,976	1,114
Stock-based compensation expense	9,525	6,186
Amortization (accretion) on investments	626	(574)
Deferred tax liabilities	105	86
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(41)	(1,875)
Operating leases, net	(2,811)	-
Accounts payable	2,066	610
Accrued expenses and other liabilities	2,299	(114)
Cash used in operating activities	(58,323)	(43,240)
Investing activities		
Purchases of equipment	(4,352)	(2,523)
Software development costs	(308)	-
Purchases of investments	(40,732)	(162,147)
Proceeds from sale or maturity of investments	140,622	109,916
Cash provided by (used in) investing activities	95,230	(54,754)
Financing activities		
Proceeds from public offering of common stock, net of issuance costs	131,330	133,570
Proceeds from the exercise of stock options	1,013	742
Payment of deferred offering costs	(336)	-
Cash provided by financing activities	132,007	134,312
Net change in cash, cash equivalents, and restricted cash	168,914	36,318
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>\$ 263,652</u>	<u>\$ 102,031</u>

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