

**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 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 November 8, 2022, TCR² Therapeutics Inc. announced its financial results for the fiscal quarter ended September 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated November 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: November 8, 2022

TCR² Therapeutics Inc.

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



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

CAMBRIDGE, Mass., November 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 third quarter ended September 30, 2022 and provided a corporate update.

"TCR² continued to execute on its streamlined corporate priorities in the last quarter and stands poised to deliver multiple clinical catalysts over the next 12 months on our two core assets, gavo-cel and TC-510," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. "In the Phase 1 trial for gavo-cel, we observed promising activity in ovarian cancer, leading us to place greater and earlier emphasis on this indication. We also established a baseline clinical profile which we believe positions gavo-cel as a first- and best-in-class anti-mesothelin monotherapy which we aim to further enhance with the addition of checkpoint inhibitors and redosing strategies in the Phase 2 portion of the trial. In addition, we have begun treating patients with our second product candidate, TC-510, a TRuC-T cell enhanced with a PD-1:CD28 chimeric switch receptor. These near-term focused activities will allow us to further maximize the number of cancer patients with access to our investigational therapies."

Recent Developments

gavo-cel:

- TCR² announced positive topline results from the complete Phase 1 dose escalation portion of the gavo-cel Phase 1/2 clinical trial for mesothelin-expressing solid tumors. Twenty-eight of the 30 patients evaluable for efficacy experienced regression of their target lesions, including eight patients who achieved a partial response (PR) by target lesion assessment, six of whom met criteria for a PR according to RECIST 1.1 criteria. Following identification of a dose-limiting toxicity (DLT) in September 2021, the study proceeded to a dose de-escalation portion and subsequently declared dose level 3 (1×10^8 cells/ m^2 following lymphodepletion) the recommended Phase 2 dose (RP2D).
- Enrollment and treatment in the Phase 2 expansion portion of the gavo-cel Phase 1/2 clinical trial is ongoing.
- TCR² presented new preclinical data at The Society for Immunotherapy of Cancer's (SITC) 37th Annual Meeting demonstrating gavo-cel maintained effector function to clear tumors and was not impaired, blocked or disrupted by functional suppression from supraphysiological levels of soluble mesothelin-related peptides.

TC-510:

- Enrollment and treatment in the Phase 1 dose escalation portion of the TC-510 Phase 1/2 clinical trial is ongoing.
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Financial Highlights

- **Cash Position:** TCR² ended the third quarter of 2022 with \$176.0 million in cash, cash equivalents, and investments compared to \$265.6 million as of December 31, 2021. Net cash used in operations was \$25.8 million for the third quarter of 2022 compared to \$19.4 million for the third quarter of 2021. TCR² continues to project 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 \$24.8 million for the third quarter of 2022 compared to \$20.3 million for the third quarter of 2021. The increase in R&D expenses was primarily due to an increase in clinical trial expenses associated with patient treatment and product manufacturing.
- **G&A Expenses:** General and administrative expenses were \$6.3 million for the third quarter of 2022 compared to \$6.0 million for the third quarter of 2021. The slight increase in general and administrative expenses was due to an increase supporting corporate activities.
- **Net Loss:** Net loss was \$30.6 million for the third quarter of 2022 compared to \$26.2 million for the third quarter of 2021.

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 15, 2022 at 5:35pm GMT (12:35pm 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.

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.

Forward-looking Statements

This press release contains forward-looking statements and information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other federal securities laws. The use of words such as "will,"

"expects," "plans," "believes," "predicts," "projects," "aims," "allows," "promising," 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, statements regarding TCR²'s plans, strategies, timelines, and expectations for its gavo-cel and TC-510 clinical trials, statements regarding IND-enabling studies on TC-520, express or implied statements regarding the therapeutic potential of gavo-cel, TC-510 and TCR²'s other product candidates in treating cancer patients and improving access to investigational therapies for cancer, and statements regarding expected cash use in 2022 and cash runway into 2024.

The expressed or implied forward-looking statements included in this press release are only current expectations, beliefs, and predictions and are subject to a number of risks, uncertainties, assumptions and important factors, 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, assumptions and important factors, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those expressed 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)

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 54,006	\$ 222,564
Investments	121,980	43,029
Prepaid expenses and other current assets	8,093	10,534
Total current assets	184,079	276,127
Property and equipment, net	29,083	17,075
Right-of-use assets, operating leases	57,704	28,283
Restricted cash	1,152	1,156
Other assets, non-current	909	730
Total assets	\$ 272,927	\$ 323,371
Liabilities and stockholders' equity		
Liabilities		
Accounts payable	\$ 2,963	\$ 2,144
Accrued expenses and other current liabilities	13,185	13,094
Operating lease liabilities	20,545	3,367
Total current liabilities	36,693	18,605
Operating lease liabilities, non-current	37,684	22,996
Other liabilities	-	293
Total liabilities	74,377	41,894
Stockholders' equity		
Common stock, \$0.0001 par value; 150,000,000 shares authorized; 38,657,061 and 38,496,484 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively.	4	4
Additional paid-in capital	639,981	631,008
Accumulated other comprehensive income (loss)	(596)	(13)
Accumulated deficit	(440,839)	(349,522)
Total stockholders' equity	198,550	281,477
Total liabilities and stockholders' equity	\$ 272,927	\$ 323,371

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,	
	2022	2021	2022	2021
Operating expenses				
Research and development	\$ 24,791	\$ 20,277	\$ 73,441	\$ 54,828
General and administrative	6,312	5,963	18,636	17,297
Total operating expenses	31,103	26,240	92,077	72,125
Loss from operations	(31,103)	(26,240)	(92,077)	(72,125)
Interest income, net	510	38	925	186
Loss before income tax expense	(30,593)	(26,202)	(91,152)	(71,939)
Income tax expense	1	42	165	129
Net loss	<u>\$ (30,594)</u>	<u>\$ (26,244)</u>	<u>\$ (91,317)</u>	<u>\$ (72,068)</u>
Per share information				
Net loss per share of common stock, basic and diluted	<u>\$ (0.79)</u>	<u>\$ (0.69)</u>	<u>\$ (2.37)</u>	<u>\$ (1.91)</u>
Weighted average shares outstanding, basic and diluted	38,620,751	38,197,929	38,567,331	37,816,345

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

	Nine Months Ended September 30,	
	2022	2021
Operating activities		
Net loss	\$ (91,317)	\$ (72,068)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	2,300	1,976
Stock-based compensation expense	8,717	9,525
(Accretion) / Amortization on investments	(403)	626
Deferred tax liabilities	(293)	105
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,618	(41)
Operating leases, net	2,445	(2,811)
Accounts payable	(637)	2,066
Accrued expenses and other liabilities	66	2,299
Cash used in operating activities	<u>(76,504)</u>	<u>(58,323)</u>
Investing activities		
Purchases of equipment	(12,681)	(4,352)
Software development costs	(330)	(308)
Purchases of investments	(215,619)	(40,732)
Proceeds from sale or maturity of investments	136,488	140,622
Cash provided by (used in) investing activities	<u>(92,142)</u>	<u>95,230</u>
Financing activities		
Proceeds from public offering of common stock, net of issuance costs	-	131,330
Proceeds from the exercise of stock options	256	1,013
Payment of deferred offering costs	(172)	(336)
Cash provided by financing activities	<u>84</u>	<u>132,007</u>
Net change in cash, cash equivalents, and restricted cash	(168,562)	168,914
Cash, cash equivalents, and restricted cash at beginning of year	223,720	94,738
Cash, cash equivalents, and restricted cash at end of period	\$ 55,158	\$ 263,652

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