

**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):
March 22, 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 March 22, 2022, TCR² Therapeutics Inc. announced its financial results for the fiscal quarter ended December 31, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated March 22, 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: March 22, 2022

TCR² Therapeutics Inc.

By: /s/ Garry E. Menzel
Garry E. Menzel
President and Chief Executive Officer



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

CAMBRIDGE, Mass., March 22, 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 fourth quarter ended December 31, 2021 and provided a corporate update.

"Consistent execution throughout the last year has positioned TCR² for a series of important readouts as we accelerate our clinical progress in 2022," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. "We were able to successfully conclude the dose escalation portion of our ongoing gavo-cel Phase 1/2 clinical trial with the identification of a RP2D and submit a protocol amendment with the FDA for the upcoming Phase 2 clinical trial. We also submitted an IND with the FDA for our first enhanced TRuC-T cell that incorporates a PD-1:CD28 switch. In the meantime, we have been identifying new clinical trial sites and expanding manufacturing capacity for the reproducible process used by Miltenyi and ElevateBio to support our clinical trials. In addition to the clinical readouts from gavo-cel and TC-510, we will continue to provide updates on the innovations in our rapidly growing pipeline, most immediately with a preclinical data presentation on our allogeneic TRuC targeting mesothelin at the AACR Annual Meeting in April."

Recent Developments

Gavo-cel:

- TCR² announced the submission of a protocol amendment to the US Food and Drug Administration (FDA) in the first quarter of 2022 for the gavo-cel Phase 2 expansion cohort, including the amendment to treat patients with gavo-cel in combination with Opdivo and/or Yervoy which forms the basis of the Company's clinical trial collaboration with Bristol Myers Squibb.

TC-510:

- TCR² announced the submission of an Investigational New Drug (IND) to the FDA in the first quarter of 2022 for TC-510, the Company's first enhanced TRuC-T cell targeting mesothelin with a PD-1:CD28 chimeric switch receptor.

Pipeline:

- TCR² announced it will present a poster at the American Association of Cancer Research (AACR) Annual Meeting 2022 featuring new preclinical data on an allogeneic (off-the-shelf) TRuC-T cell, taking place on April 8-13, 2022 in New Orleans, Louisiana. In preclinical studies, this allogeneic product candidate without an enhancement demonstrated improved anti-tumor efficacy associated with enhanced persistence and increased antigen sensitivity *in vivo* compared to donor-matched autologous TRuC-T cells targeting mesothelin. Furthermore, allogeneic TRuC-T cells generated with an additional knockout of Beta-2-microglobulin (B2M) maintained their potency.
 - TCR² announced a strategic research collaboration agreement with Arbor Biotechnologies focused on the further development of a defined set of allogeneic TRuC-T cell therapies. The collaboration leverages Arbor's proprietary CRISPR gene-editing technology, which is tailored to address the underlying pathology of genetic diseases and TCR²'s first-in-class TRuC platform, which has demonstrated clinical activity in multiple treatment-refractory mesothelin-expressing solid tumor indications with gavo-cel.
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Corporate:

- TCR² announced the appointment of experienced biotech executive Rosemary Harrison, Ph.D., as Chief Business and Strategy Officer where she will be responsible for supporting a range of activities including commercial strategy, operational planning, corporate partnerships and long-term growth opportunities.

Anticipated Milestones

- Gavo-cel:
 - Present the expanded and complete Phase 1 dataset for gavo-cel in the second quarter of 2022.
 - Initiate the Phase 2 expansion cohort of the ongoing gavo-cel Phase 1/2 clinical trial in the first half of 2022.
 - Provide an initial update from at least one of the Phase 2 expansion cohorts 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.
 - Select a lead candidate for its allogeneic program in 2022.
- Manufacturing:
 - Production of clinical trial material to commence at ElevateBio BaseCamp as capacity is increased in anticipation of demand from the Phase 2 expansion trial of gavo-cel in 2022.

Financial Highlights

- **Cash Position:** TCR² ended the fourth quarter of 2021 with \$265.6 million in cash, cash equivalents, and investments compared to \$228.0 million as of December 31, 2020. Net cash used in operations was \$23.3 million for the fourth quarter of 2021 compared to \$13.5 million for the fourth quarter of 2020. 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 \$22.4 million for the fourth quarter of 2021 compared to \$14.3 million for the fourth quarter of 2020. The research and development expenses for the fourth quarter of 2021 include restructuring costs of \$3.7 million and are partially offset by a \$2 million settlement from a vendor due to a commercial dispute. The remaining increase in R&D expenses was primarily due to an increase in headcount and manufacturing facilities.
- **G&A Expenses:** General and administrative expenses were \$5.2 million for the fourth quarter of 2021 compared to \$4.3 million for the fourth quarter of 2020. The increase in general and administrative expenses was primarily due to an increase in personnel costs.
- **Net Loss:** Net loss was \$27.7 million for the fourth quarter of 2021 compared to \$18.5 million for the fourth quarter of 2020.

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, 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 with respect to the FDA's review of our gavo-cel protocol amendments, expectations with respect to timing of our IND submission for TC-510, expectations regarding clinical data for gavo-cel and TC-510 and preclinical data for our emerging pipeline and enhancements, increased manufacturing capacity and technical capabilities, including through our manufacturing partnership with ElevateBio, LLC, expectations with respect to increased clinical trial demand and identification of additional clinical trial sites, future IND filings and clinical development plans, expected cash use in 2022 and cash runway into 2024, 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)

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 222,564	\$ 94,155
Investments	43,029	133,831
Prepaid expenses and other current assets	10,534	7,552
Total current assets	276,127	235,538
Property and equipment, net	17,075	10,013
Right-of-use assets, operating leases	28,283	-
Restricted cash	1,156	583
Other assets, non-current	730	61
Total assets	\$ 323,371	\$ 246,195
Liabilities and stockholders' equity		
Accounts payable	\$ 2,144	\$ 2,448
Accrued expenses and other current liabilities	13,094	6,392
Operating lease liabilities	3,367	-
Total current liabilities	18,605	8,840
Operating lease liabilities, non-current	22,996	-
Other liabilities	293	807
Total liabilities	41,894	9,647
Stockholders' equity		
Common stock, \$0.0001 par value; 150,000,000 shares authorized; 38,496,484 and 33,516,795 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively.	4	3
Additional paid-in capital	631,008	486,197
Accumulated other comprehensive income (loss)	(13)	63
Accumulated deficit	(349,522)	(249,715)
Total stockholders' equity	281,477	236,548
Total liabilities and stockholders' equity	\$ 323,371	\$ 246,195

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Operating expenses				
Research and development	\$ 22,411	\$ 14,298	\$ 77,239	\$ 51,980
General and administrative	5,206	4,269	22,503	16,720
Total operating expenses	<u>27,617</u>	<u>18,567</u>	<u>99,742</u>	<u>68,700</u>
Loss from operations	(27,617)	(18,567)	(99,742)	(68,700)
Interest income, net	38	191	224	1,737
Loss before income tax expense	<u>(27,579)</u>	<u>(18,376)</u>	<u>(99,518)</u>	<u>(66,963)</u>
Income tax expense	160	75	289	161
Net loss	<u>\$ (27,739)</u>	<u>\$ (18,451)</u>	<u>\$ (99,807)</u>	<u>\$ (67,124)</u>
Per share information				
Net loss per share of common stock, basic and diluted	<u>\$ (0.72)</u>	<u>\$ (0.55)</u>	<u>\$ (2.63)</u>	<u>\$ (2.40)</u>
Weighted average shares outstanding, basic and diluted	38,289,295	33,448,315	37,935,554	27,990,564

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

	Twelve Months Ended December 31,	
	2021	2020
Operating activities		
Net loss	\$ (99,807)	\$ (67,124)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	2,827	1,592
Asset impairment due to restructuring	559	-
Stock-based compensation expense	12,265	8,492
Amortization (accretion) on investments	837	(702)
Deferred tax liabilities	99	131
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,496)	(1,101)
Operating leases, net	(2,416)	-
Accounts payable	(771)	451
Accrued expenses and other liabilities	7,300	1,522
Cash used in operating activities	<u>(81,603)</u>	<u>(56,739)</u>
Investing activities		
Purchases of equipment	(11,098)	(7,164)
Software development costs	(351)	-
Purchases of investments	(50,726)	(152,812)
Proceeds from sale or maturity of investments	140,622	111,041
Cash provided by (used in) investing activities	<u>78,447</u>	<u>(48,935)</u>
Financing activities		
Proceeds from public offering of common stock, net of issuance costs	131,330	133,571
Proceeds from the exercise of stock options	1,217	1,189
Payment of deferred offering costs	(409)	(61)
Cash provided by financing activities	<u>132,138</u>	<u>134,699</u>
Net change in cash, cash equivalents, and restricted cash	128,982	29,025
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>\$ 223,720</u>	<u>\$ 94,738</u>

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