

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 11, 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
(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 11, 2021, TCR2 Therapeutics Inc. announced its financial results for the fiscal year ended December 31, 2020. 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 11, 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: March 11, 2021

TCR² Therapeutics Inc.

By: /s/ Mayur (Ian) Somaiya

Mayur (Ian) Somaiya
Chief Financial Officer



TCR² Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update

- Preliminary safety, efficacy and translational data from gavo-cel Phase 1 trial at AACR 2021
- Preclinical data on autologous CD70 and allogeneic mesothelin TRuC data at AACR 2021
- Raised gross proceeds of \$140M in a follow-on offering in January; extended cash runway into 2024

CAMBRIDGE, Mass., March 11, 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 fourth quarter ended December 31, 2020 and provided a corporate update.

"2020 was a transformative year for TCR², with initial clinical data on our lead program, gavo-cel, establishing our leadership position in solid tumors. On the back of encouraging RECIST responses in refractory mesothelioma and ovarian cancer, we were able to strengthen our balance sheet and diversify our investor base, extending our cash runway into 2024 to support our goal of saving the lives of cancer patients," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. "We now look to accelerate the development of gavo-cel in 2021 by identifying the recommended Phase 2 dose, initiating the expansion portion of the trial and increasing our manufacturing capacity. We will also provide updates on our rapidly growing pipeline, most immediately with preclinical data presentations at the AACR conference on our allogeneic mesothelin TRuC and our CD70 autologous TRuC."

Recent Developments

- TCR² reported a 38% Overall Response Rate with three RECIST partial responses (PRs) (2 confirmed and 1 unconfirmed PRs) from patients in the dose escalation portion of the gavo-cel Phase 1/2 clinical trial, including the first ovarian cancer patient to ever achieve a PR with an engineered cell therapy and one mesothelioma patient achieving a complete metabolic response.
 - TCR² completed an upsized \$140M follow-on offering.
 - TCR² announced preliminary safety and efficacy data with a focus on translational data of gavo-cel in patients with treatment refractory mesothelin overexpressing solid tumors will be presented in an e-poster presentation at the American Association of Cancer Research (AACR) Virtual Annual Meeting on Saturday, April 10, 2021.
 - TCR² continues to treat patients in the dose escalation portion of the TC-110 Phase 1/2 clinical trial.
 - TCR² announced new preclinical data from its allogeneic TRuC-T cell targeting mesothelin highlighting a lack of alloreactivity, reduced risk of host rejection, upregulation of activation markers, secretion of cytokines and clearance of tumors cells will be presented in an e-poster presentation at the AACR Virtual Annual Meeting on Saturday, April 10, 2021.
 - TCR² announced new preclinical data from its TRuC-T cell targeting CD70 highlighting T cell expansion, improved memory phenotype, significant anti-tumor efficacy in multiple xenograft mouse models with no
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evidence of *in vivo* fratricide will be presented in an e-poster presentation at the AACR Virtual Annual Meeting on Saturday, April 10, 2021.

- TCR² announced the appointment of Shawn Tomasello to its Board of Directors. Ms. Tomasello served as Chief Commercial Officer of Kite Pharma where she oversaw the global commercialization of Yescarta, from 2015 to 2018 including through its acquisition by Gilead for \$11.9 billion in October 2017.

Anticipated Milestones

- TCR² to present additional safety, efficacy and translational data from the Phase 1 portion of the gavo-cel Phase 1/2 clinical trial for patients with mesothelin-expressing solid tumors throughout 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 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 2021.
- TCR² plans to select a development candidate for its allogeneic program in 2021.
- TCR² anticipates additional pipeline updates throughout 2021.
- TCR² anticipates production of gavo-cel clinical trial material from ElevateBio in 2021.
- TCR² anticipates MHRA certification of its manufacturing facility in Stevenage, UK, in mid-2021.

Financial Highlights

- **Cash Position:** TCR² ended 2020 with \$228.0 million in cash, cash equivalents, and investments compared to \$158.1 million as of December 31, 2019. Year-end 2020 cash balance does not reflect gross proceeds of \$140 million from our equity offering in January. Net cash used in operations was \$56.7 million for 2020 compared to \$41.4 million for 2019. TCR² projects net cash use of \$80-90 million for 2021.
- **R&D Expenses:** Research and development expenses were \$52.0 million for 2020 compared to \$37.5 million for 2019. The increase in R&D expenses is primarily related to increase in headcount, activities related to the Phase 1/2 clinical trial of TC-210 and activities related to the Phase 1/2 clinical trial of TC-110.
- **G&A Expenses:** General and administrative expenses were \$16.7 million for 2020 compared to \$13.9 million for 2019. The increase in general and administrative expenses was primarily due to an increase in personnel costs.
- **Net Loss:** Net loss was \$67.1 million for 2020 compared to \$47.6 million for 2019, driven predominantly by increased personnel expenses.

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 solid tumors or hematological malignancies. 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, TC-210, 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 for interim updates for the gavo-cel and TC-110 clinical trials, timing for the certification of our manufacturing facility in Stevenage, UK, increased manufacturing capacity and technical capabilities, including relating to 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)

	December 31,	
	2020	2019
Assets		
Current assets		
Cash and cash equivalents	\$ 94,155	\$ 65,296
Investments	133,831	92,828
Prepaid expenses and other current assets	7,552	5,061
Total current assets	235,538	163,185
Property and equipment, net	10,013	4,926
Restricted cash	583	417
Deferred offering costs	61	-
Total assets	<u>\$ 246,195</u>	<u>\$ 168,528</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 2,448	\$ 2,483
Accrued expenses and other current liabilities	6,392	5,050
Total current liabilities	8,840	7,533
Other liabilities	807	546
Total liabilities	9,647	8,079
Stockholders' equity		
Common stock, \$0.0001 par value; 150,000,000 shares authorized; 33,516,795 and 24,050,936 shares issued; 33,516,795 and 23,981,109 shares outstanding at December 31, 2020 and 2019, respectively.	3	2
Additional paid-in capital	486,197	342,896
Accumulated other comprehensive income	63	142
Accumulated deficit	(249,715)	(182,591)
Total stockholders' equity	236,548	160,449
Total liabilities and stockholders' equity	<u>\$ 246,195</u>	<u>\$ 168,528</u>

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,	
	2020	2019	2020	2019
Operating expenses				
Research and development	\$ 14,298	\$ 9,392	\$ 51,980	\$ 37,488
General and administrative	4,269	4,179	16,720	13,894
Total operating expenses	18,567	13,571	68,700	51,382
Loss from operations	(18,567)	(13,571)	(68,700)	(51,382)
Interest income, net	191	846	1,737	3,885
Loss before income tax expense	(18,376)	(12,725)	(66,963)	(47,497)
Income tax expense	75	102	161	102
Net loss	(18,451)	(12,827)	(67,124)	(47,599)
Accretion of redeemable convertible preferred stock to redemption value	-	-	-	\$ (49,900)
Net loss attributable to common stockholders	\$ (18,451)	\$ (12,827)	\$ (67,124)	\$ (97,499)
Per share information				
Net loss per share of common stock, basic and diluted	\$ (0.55)	\$ (0.54)	\$ (2.40)	\$ (4.62)
Weighted average shares outstanding, basic and diluted	33,448,315	23,961,960	27,990,564	21,104,195

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

	<u>Twelve Months Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Operating activities		
Net loss	\$ (67,124)	\$ (47,599)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,592	862
Stock-based compensation expense	8,492	6,702
Accretion on investments	(702)	(225)
Deferred tax liabilities	131	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,101)	(3,057)
Accounts payable	451	(179)
Accrued expenses and other liabilities	1,522	2,137
Cash used in operating activities	<u>(56,739)</u>	<u>(41,359)</u>
Investing activities		
Purchases of equipment	(7,164)	(3,879)
Purchases of investments	(152,812)	(126,261)
Proceeds from sale or maturity of investments	111,041	109,725
Cash used in investing activities	<u>(48,935)</u>	<u>(20,415)</u>
Financing activities		
Proceeds from public offering of common stock, net of issuance costs	133,571	79,132
Proceeds from the exercise of stock options	1,189	391
Deferred offering costs	(61)	-
Cash provided by financing activities	<u>134,699</u>	<u>79,523</u>
Net change in cash, cash equivalents, and restricted cash	29,025	17,749
Cash, cash equivalents, and restricted cash at beginning of year	65,713	47,964
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 94,738</u>	<u>\$ 65,713</u>

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