

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 23, 2023

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 23, 2023, TCR² Therapeutics Inc. announced its financial results for the fiscal quarter ended December 31, 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 March 23, 2023
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 23, 2023

TCR² Therapeutics Inc.

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



TCR² Therapeutics Reports Fourth Quarter and Full-Year 2022 Financial Results and Provides Corporate Update

- *TCR² and Adaptimmune announce strategic combination to create a preeminent cell therapy company focused on treating solid tumors*
- *Following the expected Q2 2023 closing of the all-stock transaction, the combined company's cash runway is expected to extend into 2026*

CAMBRIDGE, Mass., March 23, 2023- TCR² Therapeutics Inc. (Nasdaq: TCRR) (TCR² or the Company), a clinical-stage cell therapy company with a pipeline of novel next-generation T cell therapies for patients suffering from solid tumors, today announced fourth quarter and full-year 2022 financial results and provided a corporate update.

"Focus and specialization are critical in the cell therapy space. The strategic combination with Adaptimmune and the operating benefits are highly compelling for both Adaptimmune and TCR² shareholders. Our complementary technology platforms are designed to treat solid tumors which represents a substantial market opportunity largely unaddressed by cell therapies. The combination of our two companies provides a strong foundation to commercialize curative therapies for people with cancer," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics.

Recent Developments

- TCR² announced a strategic combination with Adaptimmune Therapeutics plc (Adaptimmune) to create a preeminent cell therapy company for solid tumors. The two companies entered into a definitive agreement under which Adaptimmune will combine with TCR² in an all-stock transaction. The transaction is expected to close in the second quarter of 2023, subject to shareholder approval and satisfaction or waiver of other closing conditions. Following the closing of the transaction, Adaptimmune shareholders will own approximately 75% and TCR² stockholders will own approximately 25% of the combined company. As a result, and following the closing of the transaction, it is anticipated that the combined company's cash runway will extend into 2026.
- TCR² published preclinical gavo-cel data in *Onc Immunology*. Research showed that gavo-cel more rapidly infiltrated and eliminated mesothelin-positive tumors of various histologies while producing less pro-inflammatory cytokines than second-generation mesothelin-targeted CAR T cells.
- TCR² reprioritized its pipeline to focus on gavo-cel in ovarian cancer and second-generation programs TC-510 and TC-520. In connection with the reprioritization, TCR² reduced its workforce by approximately 40 percent.

Anticipated Milestones

gavo-cel:

- First readout from the ongoing Phase 2 portion of the gavo-cel Phase 1/2 clinical trial in ovarian cancer in combination with checkpoint inhibitors and redosing strategies anticipated in the second half of 2023.
- Interim update, including key translational data, in patients with mesothelioma treated with gavo-cel in combination with checkpoint inhibitors in the Phase 2 portion of the gavo-cel Phase 1/2 clinical trial before the focus was narrowed to ovarian cancer anticipated midyear 2023.

- Tumor regression has been observed in 93% of patients in the Phase 1 trial. The response rate was 29% in patients with ovarian cancer with a median progression free survival (PFS) of 5.8 months and a median overall survival (OS) of 8.1 months. The response rate in mesothelioma was 21% with a median PFS of 5.9 months and a median OS of 11.2 months.

TC-510:

- First data readout from the Phase 1 trial with TC-510 for patients with ovarian, malignant pleural mesothelioma, pancreatic, colorectal, or triple-negative breast cancer anticipated in the second half of 2023.

Financial Highlights

- **Cash Position:** TCR² ended the fourth quarter of 2022 with \$149.2 million in cash, cash equivalents, and investments compared to \$265.6 million as of December 31, 2021. Net cash used in operations was \$25.0 million for the fourth quarter of 2022 compared to \$23.3 million for the fourth quarter of 2021.
- **R&D Expenses:** Research and development (R&D) expenses were \$25.7 million for the fourth quarter of 2022 compared to \$18.8 million for the fourth quarter of 2021. The increase in R&D expenses was primarily due to increased spending on clinical programs.
- **Impairment and Restructuring Expenses:** Impairment expenses were \$29.9 million for the fourth quarter of 2022 compared to \$3.7 million for the fourth quarter of 2021. The impairment charges during 2022 are primarily related to the Rockville manufacturing facility which have been reclassified as held for sale as of December 31, 2022.
- **G&A Expenses:** General and administrative (G&A) expenses were \$5.8 million for the fourth quarter of 2022 compared to \$5.2 million for the fourth quarter of 2021. The increase in G&A expenses was primarily due to an increase in personnel costs.
- **Net Loss:** Net loss was \$60.5 million for the fourth quarter of 2022 compared to \$27.7 million for the fourth quarter of 2021.

About gavo-cel, TC-510, and TC-520

Our most advanced program, gavo-cel, targets tumors that express the protein mesothelin.

TC-510 is an enhanced version of gavo-cel that co-expresses a PD-1:CD28 chimeric switch receptor that the Company believes may lead to deeper responses and more durable benefit.

TC-520 is the Company's first TRuC-T cell targeting CD-70-expressing solid and liquid tumors which incorporates IL-15 pathway enhancements designed to improve T-cell persistence. TCR² is currently advancing TC-520 to Investigational New Drug (IND) status.

About TCR² Therapeutics

TCR² Therapeutics Inc. is a clinical-stage cell therapy company developing a pipeline of novel next generation T cell therapies for 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 TCR²'s other product candidates, including potential improvements in efficacy, safety and durability in the Phase 2 portion of the gavo-cel trial, expectations regarding future growth and prospects, future clinical development plans and anticipated timing of data updates, the development of the Company's TRuC-T cells, including their potential characteristics, applications and clinical utility, the potential therapeutic applications of the TCR²'s TruC-T cell platform, expected cash runway of the combined company following the closing of the proposed transaction with Adaptimmune, expected cost savings related to the Company's reduction in workforce, the benefits of the transaction with Adaptimmune and expectations regarding the timing for closing of the transaction with Adaptimmune.

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 as to the timing for completion of the transaction with Adaptimmune; uncertainties as to TCR²'s and/or Adaptimmune's ability to obtain the approval of Adaptimmune's shareholders or TCR²'s stockholders required to consummate the transaction with Adaptimmune; the possibility that competing offers will be made by third parties; the occurrence of events that may give rise to a right of one or both of Adaptimmune and TCR² to terminate the merger agreement; the possibility that various closing conditions for the transaction with Adaptimmune may not be satisfied or waived on a timely basis or at all, including the possibility that a governmental entity may prohibit, delay, or refuse to grant approval, if required, for the consummation of the transaction with Adaptimmune (or only grant approval subject to adverse conditions or limitations); the difficulty of predicting the timing or outcome of consents or regulatory approvals or actions, if any; the possibility that the transaction with Adaptimmune may not be completed in the time frame expected by Adaptimmune and TCR², or at all; the risk that Adaptimmune and TCR² may not realize the anticipated benefits of the transaction with Adaptimmune in the time frame expected, or at all; the effects of the transaction with Adaptimmune on relationships with Adaptimmune's or TCR²'s employees, business or collaboration partners or governmental entities; the ability to retain and hire key personnel; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction with Adaptimmune; significant or unexpected costs, charges or expenses resulting from the transaction with Adaptimmune; the potential impact of unforeseen liabilities, future capital expenditures, revenues, costs, expenses, earnings, synergies, economic performance, indebtedness, financial condition and losses on the future prospects, business and management strategies for the management, expansion and growth of the combined business after the consummation of the transaction with Adaptimmune; potential negative effects related to this announcement or the consummation of the transaction with Adaptimmune on the market price of Adaptimmune's American Depositary Shares or TCR²'s common stock and/or Adaptimmune's or TCR²'s operating or financial results; uncertainties as to the long-term value of Adaptimmune's American Depositary Shares (and the ordinary shares represented thereby), including the dilution caused by Adaptimmune's issuance of additional American Depositary Shares (and the ordinary shares represented thereby) in connection with the transaction with Adaptimmune; unknown liabilities related to Adaptimmune or TCR²; the nature, cost and outcome of any litigation and other legal proceedings involving Adaptimmune, TCR² or their respective directors, including any legal proceedings related to the transaction with Adaptimmune; risks related to global as well as local political and economic conditions, including interest rate and currency exchange rate fluctuations; potential delays or failures related to research and/or development of Adaptimmune's or TCR²'s programs or product candidates; risks related to any loss of Adaptimmune's or TCR²'s

patents or other intellectual property rights; any interruptions of the supply chain for raw materials or manufacturing for Adaptimmune or TCR²'s product candidates, the nature, timing, cost and possible success and therapeutic applications of product candidates being developed by Adaptimmune, TCR² and/or their respective collaborators or licensees; the extent to which the results from the research and development programs conducted by Adaptimmune, TCR², and/or their respective collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; uncertainty of the utilization, market acceptance, and commercial success of Adaptimmune or TCR²'s product candidates, and the impact of studies (whether conducted by Adaptimmune, TCR² or others and whether mandated or voluntary) on any of the foregoing; unexpected breaches or terminations with respect to Adaptimmune's or TCR²'s material contracts or arrangements; risks related to competition for Adaptimmune's or TCR²'s product candidates; Adaptimmune's or TCR²'s ability to successfully develop or commercialize Adaptimmune's or TCR²'s product candidates; Adaptimmune's, TCR²'s, and their collaborators' abilities to continue to conduct current and future developmental, preclinical and clinical programs; potential exposure to legal proceedings and investigations; risks related to changes in governmental laws and related interpretation thereof, including on reimbursement, intellectual property protection and regulatory controls on testing, approval, manufacturing, development or commercialization of any of Adaptimmune's or TCR²'s product candidates; unexpected increase in costs and expenses with respect to the proposed transaction or Adaptimmune's or TCR²'s business or operations; and risks and uncertainties related to epidemics, pandemics or other public health crises and their impact on Adaptimmune's and TCR²'s respective businesses, operations, supply chain, patient enrollment and retention, preclinical and clinical trials, strategy, goals and anticipated milestones, risks related to global economic conditions, including disruptions in the banking industry, 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. TCR² undertakes 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.

Media Contact:

Kathy Vincent
kathy@kathyvincent.com

Investor Contact:

Eric Sullivan
Chief Financial Officer
eric.sullivan@tcr2.com

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

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 32,746	\$ 222,564
Investments	116,433	43,029
Prepaid expenses and other current assets	5,155	10,534
Assets held for sale	23,287	-
Total current assets	177,621	276,127
Property and equipment, net	6,166	17,075
Right-of-use assets, operating leases	22,510	28,283
Restricted cash	1,152	1,156
Other assets, non-current	787	730
Total assets	<u>\$ 208,236</u>	<u>\$ 323,371</u>
Liabilities and stockholders' equity		
Liabilities		
Accounts payable	\$ 2,793	\$ 2,144
Accrued expenses and other current liabilities	10,823	13,094
Operating lease liabilities	21,834	3,367
Operating lease liabilities related to assets held for sale	28,611	-
Total current liabilities	64,061	18,605
Operating lease liabilities, non-current	3,316	22,996
Other liabilities	-	293
Total liabilities	67,377	41,894
Stockholders' equity		
Common stock, \$0.0001 par value; 150,000,000 shares authorized; 39,203,366 and 38,496,484 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively.	4	4
Additional paid-in capital	642,644	631,008
Accumulated other comprehensive income (loss)	(445)	(13)
Accumulated deficit	(501,344)	(349,522)
Total stockholders' equity	140,859	281,477
Total liabilities and stockholders' equity	<u>\$ 208,236</u>	<u>\$ 323,371</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,	
	2022	2021	2022	2021
Operating expenses				
Research and development	\$ 25,736	\$ 18,750	\$ 98,643	\$ 73,578
Impairments and restructuring charges	29,883	3,661	30,417	3,661
General and administrative	5,803	5,206	24,439	22,503
Total operating expenses	61,422	27,617	153,499	99,742
Loss from operations	(61,422)	(27,617)	(153,499)	(99,742)
Interest income, net	1,013	38	1,938	224
Loss before income tax expense	(60,409)	(27,579)	(151,561)	(99,518)
Income tax expense	96	160	261	289
Net loss	\$ (60,505)	\$ (27,739)	\$ (151,822)	\$ (99,807)
Per share information				
Net loss per share of common stock, basic and diluted	\$ (1.56)	\$ (0.72)	\$ (3.93)	\$ (2.63)
Weighted average shares outstanding, basic and diluted	38,808,447	38,289,295	38,628,105	37,935,554

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

	Twelve Months Ended December 31,	
	2022	2021
Operating activities		
Net loss	\$ (151,822)	\$ (99,807)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	3,046	2,827
Impairment and restructuring charges	27,450	2,960
Stock-based compensation expense	11,380	12,265
(Accretion) / Amortization on investments	(802)	837
Deferred tax liabilities	(293)	99
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	5,557	(2,496)
Operating leases, net	2,680	(2,416)
Accounts payable	1,166	(771)
Accrued expenses and other liabilities	177	4,899
Cash used in operating activities	(101,461)	(81,603)
Investing activities		
Purchases of equipment	(15,122)	(11,098)
Software development costs	(330)	(351)
Purchases of investments	(267,522)	(50,726)
Proceeds from sale or maturity of investments	194,488	140,622
Cash provided by (used in) investing activities	(88,486)	78,447
Financing activities		
Proceeds from public offering of common stock, net of issuance costs	-	131,330
Proceeds from the exercise of stock options	256	1,217
Payment of deferred offering costs	(131)	(409)
Cash provided by financing activities	125	132,138
Net change in cash, cash equivalents, and restricted cash	(189,822)	128,982
Cash, cash equivalents, and restricted cash at beginning of year	223,720	94,738
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 33,898</u>	<u>\$ 223,720</u>

#

