# 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):**
**May 13, 2019**

# TCR$^2$ THERAPEUTICS INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-38811** | **47-4152751** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (I.R.S Employer Identification No.) |

**100 Binney Street**
**Suite 710**
**Cambridge, Massachusetts 02142**
(Address of principal executive offices, including 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))

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 x

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. ☐

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 |

**Item 2.02 Results of Operations and Financial Condition**

On May 13, 2019, TCR$^2$ Therapeutics Inc. announced its financial results for the quarter ended March 31, 2019. 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 May 13, 2019 |

**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.

Dated: May 13, 2019

**TCR$^2$ Therapeutics Inc.**

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

# TCR$^2$ Therapeutics Reports First Quarter 2019 Financial Results and Provides Corporate Update

- Initiated Phase 1/2 clinical trial for TC-210, TCR$^2$'s lead product candidate targeting mesothelin expressing solid tumors
- On track to file an IND for TCR$^2$'s lead hematology product candidate, TC-110, in patients with CD19+ non-Hodgkin lymphomas and leukemias in 2H 2019
- Recent publication in *Nature Communications* and scientific presentations highlight advantages of the Company's TRuC™-T cell platform
- Established occupancy of manufacturing suite at Cell and Gene Therapy Catapult in the UK

**CAMBRIDGE, Mass.,** *May 13, 2019* - TCR$^2$ Therapeutics Inc. (Nasdaq: TCRR), a clinical-stage immunotherapy company developing the next generation of novel T cell therapies for patients suffering from cancer, today announced financial results for the first quarter ended March 31, 2019 and provided a corporate update.

"In our first quarter as a public company, TCR$^2$ has continued to execute our vision and objectives," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR$^2$ Therapeutics. "During the quarter, we initiated our Phase 1/2 trial for TC-210, progressed TC-110 toward IND submission in the second half of 2019, and highlighted the differentiation of our novel TRuC-T cells in scientific presentations at Keystone Symposia on Cancer Immunotherapy, AACR and CAR-T Congress USA. These preclinical studies underscore TRuC-T cells' greater anti-tumor activity, longer persistence, and less cytokine release compared to CAR-T cells."

**Recent Developments**

- In January 2019, the FDA cleared the IND for TC-210. TCR$^2$ initiated its Phase 1/2 trial to treat patients with mesothelin-positive non-small cell lung cancer (NSCLC), ovarian cancer, malignant pleural/peritoneal mesothelioma, and cholangiocarcinoma. TCR$^2$ anticipates providing an update on the trial before the end of the 2019.
- In February 2019, TCR$^2$ completed an initial public offering pursuant to which it issued and sold 5,750,000 shares of common stock, including full exercise of the underwriters' over-allotment option, resulting in net proceeds of $80.2 million after deducting underwriting discounts and commissions.
- In February 2019, the FDA granted orphan drug designation to TC-210 for the treatment of mesothelioma.
- In February 2019, TCR$^2$ held a pre-IND meeting with the FDA and remains on track to submit an IND for TC-110 in patients with CD19+ non-Hodgkin lymphomas and leukemias in the second half of 2019.
- In February 2019, the United States Patent and Trademark Office issued U.S. Patent No.: 10,208,285, with claims covering TCR$^2$'s TRuC-T cells that express anti-mesothelin TCR fusion proteins, including TC-210.
- In March 2019, TCR$^2$ presented two poster presentations at the American Association for Cancer Research (AACR) Annual Meeting 2019 featuring preclinical data for TC-110 and TC-210.
- In March 2019, TCR$^2$ established occupancy of its manufacturing suite at Cell and Gene Therapy (CGT) Catapult in the UK.
- In May 2019, TCR$^2$ published preclinical data in the peer-reviewed journal *Nature Communications* demonstrating the advantages of TRuC-T cells compared to CAR-T cells. In the paper entitled, "Synthetic TRuC receptors engaging the complete T cell receptor for potent anti-tumor response," the findings, consistent with the Company's previously reported preclinical data, support the Company's belief that its product candidates could improve the observed efficacy and safety of other adoptive T-cell therapies in development.

**TC-210 Clinical Trial Design**

- The Phase 1/2 clinical trial (NCT03907852) is evaluating the safety and efficacy of TC-210, TCR$^2$'s T-cell receptor fusion construct against mesothelin. The trial is enrolling patients with mesothelin expressing non-small cell lung cancer (NSCLC), ovarian cancer, cholangiocarcinoma, and malignant pleural/peritoneal mesothelioma.
- The Phase 1 portion of the clinical trial utilizes a 3+3 design with four escalating dose levels for TC-210. At each dose level, TC-210 will be first tested without lymphodepletion and then following lymphodepleting chemotherapy. The primary objective for the study is patient safety with a key secondary objective to determine the recommended Phase 2 dose (RP2D). In addition to standard measures of safety and efficacy, translational work includes assessment of patients' tissues for expansion, trafficking, and persistence of TC-210 T cells.
- In the Phase 2 portion of the clinical trial, approximately 50 patients are planned to receive TC-210 at the RP2D in four distinct cohorts according to their cancer diagnosis: NSCLC, ovarian cancer, malignant pleural/peritoneal mesothelioma and cholangiocarcinoma. Each cohort includes ten patients, except the NSCLC cohort which includes 20 patients with eight patients to receive TC-210 as single agent and 12 to receive TC-210 in combination with a programmed cell death 1 (PD-1) blocking antibody.

**Summary of Recent Presentations and Publications**

- **Keystone Symposia on Molecular and Cellular Biology: Cancer Immunotherapy**
  - Robert Hofmeister, Ph.D., Chief Scientific Officer, delivered an oral presentation, "Preclinical Evaluation of TC-210, a Mesothelin-Specific T Cell Receptor (TCR) Fusion Construct (TRuC™) T Cells for the Treatment of Solid Tumors."
- **AACR Annual Meeting 2019**
  - The Company presented two posters on the preclinical evaluation of TC-210 and TC-110 demonstrating superior *in vivo* anti-tumor activity compared to CAR-T cells with the same binders, including evidence that the anti-tumor activity of TRuC-T cells, both *in vitro* and *in vivo*, does not require added co-stimulatory signals.
- **CAR-T Congress USA 2019**
  - Robert Hofmeister, Ph.D., Chief Scientific Officer, delivered an oral presentation on the features of the TRuC-T cell platform, "Utilizing the Entire T Cell Receptor Independent of HLA for a Broad and Controlled Anti-Tumor Response."
- ***Nature Communications***
  - The Company published preclinical data demonstrating the advantages of TRuC-T cells compared to CAR-T cells. In the paper entitled, "Synthetic TRuC receptors engaging the complete T cell receptor for potent anti-tumor response," the findings, consistent with the TCR$^2$'s previously reported preclinical data, support the Company's belief that its product candidates could improve the observed efficacy and safety of other adoptive T-cell therapies in development.

**Financial Highlights**

- **Cash Position:** TCR$^2$ ended 1Q 2019 with $191.7 million in cash, cash equivalents, and investments compared to $123.2 million as of December 31, 2018. Net cash from the Company's initial public offering in 1Q 2019 was $80.2 million. Net cash used in operations was $10.8 million for 1Q 2019 compared to $3.0 million in 1Q 2018. TCR$^2$ projects net cash use of $45-55 million in 2019.

- **R&D Expenses:** Research and development expenses were $7.9 million for the first quarter of 2019 compared to $2.9 million for the first quarter of 2018. The increase in R&D expenses is primarily related to increase in headcount and activities related to the start of the Phase 1/2 clinical trial of the Company's lead solid tumor product candidate, TC-210.

- **G&A Expenses:** General and administrative expenses were $2.9 million for the first quarter of 2019 compared to $1.2 million for the first quarter of 2018. The increase in general and administrative expenses was primarily due to an increase in personnel costs and cost associated with operations as a public company.

- **Net loss:** Net loss was $9.9 million for the first quarter of 2019 compared to $4.0 million for the first quarter of 2018, driven predominantly by increased R&D expense in the quarter.

**Upcoming Events**

TCR$^2$ Therapeutics management are scheduled to present at the following upcoming conferences.

- **Jefferies Global Healthcare Conference:** Alfonso Quintás Cardama, M.D., Chief Medical Officer and Ian Somaiya, Chief Financial Officer, will present on Wednesday, June 5th, 2019 at 10:30am ET in New York, NY.
- **BMO 2019 Prescriptions for Success Healthcare Conference:** Robert Hofmeister, Ph.D., Chief Scientific Officer, will present on Thursday, June 25, 2019 at 3:40pm ET in New York, NY.

**Conference Call Details**

TCR$^2$ will host a conference call and live audio webcast to discuss results and provide a corporate update at 5:00 PM ET today. The live call may be accessed by dialing (866) 220-8062 for domestic calls or (470) 495-9169 for international calls and referencing conference ID 2063908. A live audio webcast for the conference call will be available on the Investors page of the Company's website at investors.tcr2.com. Following the conclusion of the call, the webcast will be available for replay for 30 days.

**About TCR$^2$ Therapeutics**

TCR$^2$ Therapeutics Inc. is a clinical-stage immunotherapy company developing the next generation of novel T cell therapies for patients suffering from cancer. TCR$^2$'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 exhibiting lower levels of cytokine release. The Company's lead TRuC-T cell product candidate, 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. For more information about TCR$^2$, 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 TCR$^2$'s plans to submit an IND for TC-110 in the second half of 2019; the anticipation of an update for TC-210 in the fourth quarter of 2019; expectations for the initiation of operations at TCR$^2$'s Catapult facility; planned dosing cohorts and the number of patients to be treated in TCR$^2$'s Phase 1/2 clinical trial for TC-210 and related effects on TCR$^2$'s manufacturing capacity in the future; and TCR$^2$'s plans to advance its first three TRuC-T cell product candidates into clinical trials by the first half of 2020.

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; TCR$^2$'s ability to maintain sufficient manufacturing capabilities to support its research, development and commercialization efforts, whether TCR$^2$'s cash resources will be sufficient to fund TCR$^2$'s foreseeable and unforeseeable operating expenses and capital expenditure requirements; and other risks set forth under the caption "Risk Factors" in TCR$^2$'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 TCR$^2$ 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 TCR$^2$ 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)**

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 46,405 | $ 47,674 |
| Investments | 115,251 | 75,493 |
| Prepaid expenses and other current assets | 3,929 | 2,326 |
| Total current assets | 165,585 | 125,493 |
| | | |
| Property and equipment, net | 1,936 | 1,638 |
| Investments, non-current | 30,048 | — |
| Restricted cash | 290 | 290 |
| Deferred offering costs | — | 2,012 |
| Total assets | $ 197,859 | $ 129,433 |
| | | |
| **Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)** | | |
| Accounts payable | $ 2,830 | $ 2,663 |
| Accrued expenses and other current liabilities | 2,527 | 2,802 |
| Total current liabilities | 5,357 | 5,465 |
| | | |
| Other liabilities | 455 | 434 |
| Total liabilities | 5,812 | 5,899 |
| | | |
| Redeemable convertible preferred stock | | |
| Series A preferred stock, $0.0001 par value; no shares and 45,000,000 authorized at March 31, 2019 and December 31, 2018; no shares and 44,500,001 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively. | — | 72,980 |
| Series B preferred stock, $0.0001 par value; no shares and 62,500,000 authorized at March 31, 2019 and December 31, 2018, respectively; no shares and 62,500,000 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively. | — | 136,250 |
| Total redeemable convertible preferred stock | — | 209,230 |
| | | |
| Stockholders' equity (deficit) | | |
| Preferred stock, $0.0001 par value. 10,000,000 and no shares authorized, issued or outstanding at March 31, 2019 and December 31, 2018, respectively. | — | — |
| Common stock, $0.0001 par value; 150,000,000 and 20,988,730 shares authorized at March 31, 2019 and December 31, 2018, respectively; 23,940,025 and 914,602 shares issued at March 31, 2019 and December 31, 2018, respectively; 23,792,193 and 726,994 shares outstanding at March 31, 2019 and December 31, 2018, respectively. | 2 | — |
| Additional paid-in capital | 336,939 | — |
| Accumulated other comprehensive income (loss) | 1 | (106) |
| Accumulated deficit | (144,895) | (85,590) |
| Total stockholders' equity (deficit) | 192,047 | (85,696) |
| Total liabilities, redeemable preferred stock and stockholders' equity (deficit) | $ 197,859 | $ 129,433 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2019** | **2018** |
| Operating expenses | | |
| Research and development | $ 7,889 | $ 2,893 |
| General and administrative | 2,886 | 1,220 |
| Total operating expenses | 10,775 | 4,113 |
| Loss from operations | (10,775) | (4,113) |
| | | |
| Interest income, net | 872 | 127 |
| Net loss | (9,903) | (3,986) |
| | | |
| Accretion of redeemable convertible preferred stock to redemption value | (49,900) | (10,833) |
| Net loss attributable to common stockholders | $ (59,803) | $ (14,819) |
| | | |
| Per share information | | |
| Net loss per share attributable to common stockholders, basic and diluted | $ (4.85) | $ (28.90) |
| | | |
| Weighted average shares outstanding, basic and diluted | 12,328,805 | 512,685 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2019** | **2018** |
| Operating activities: | | |
| Net loss | $ (9,903) | $ (3,986) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Depreciation and amortization | 135 | 76 |
| Stock-based compensation expense | 1,141 | 283 |
| Accretion on investments | (131) | (18) |
| Changes in operating assets and liabilities: | | |
| Interest receivable on investments | (157) | (51) |
| Prepaid expenses and other current assets | (1,207) | 583 |
| Accounts payable | (401) | 221 |
| Accrued expenses and other liabilities | (310) | (120) |
| Cash used in operating activities | (10,833) | (3,012) |
| | | |
| Investing activities: | | |
| Purchase of investments | (86,626) | (13,369) |
| Proceeds from maturity of investments | 16,819 | — |
| Purchases of equipment | (188) | (368) |
| Cash used in investing activities | (69,995) | (13,737) |
| | | |
| Financing activities: | | |
| Proceeds from the sale of Series B preferred stock | — | 120,000 |
| Proceeds from initial public offering, net of issuance costs | 80,213 | — |
| Proceeds from the exercise of stock options | — | 219 |
| Deferred offering costs | (654) | (3) |
| Payment of issuance costs | — | (150) |
| Cash provided by financing activities | 79,559 | 120,066 |
| | | |
| Net change in cash, cash equivalents, and restricted cash | (1,269) | 103,317 |
| Cash, cash equivalents, and restricted cash at beginning of year | 47,964 | 20,101 |
| Cash, cash equivalents, and restricted cash at end of period | $ 46,695 | $ 123,418 |

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