

**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):
April 1, 2019

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, 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

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 April 1, 2019, TCR² Therapeutics Inc. announced its financial results for the quarter and full year ended December 31, 2018. 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 April 1, 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: April 1, 2019

TCR² Therapeutics Inc.

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



TCR² Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Corporate Update

- U.S. Food and Drug Administration (FDA) cleared TCR²'s investigational new drug (IND) application for its lead solid tumor candidate TC-210; Company initiated Phase 1/2 clinical trial
- Initial public offering completed in February raised approximately \$80.2 million in net proceeds
- Held pre-IND meeting with FDA for lead hematology candidate TC-110
- Patent issued with claims covering TCR²'s TRuC™-T cells that express anti-mesothelin T cell receptor fusion proteins including TC-210

Cambridge, Mass., April 1, 2019 - TCR² Therapeutics Inc. (Nasdaq: TCRR), a clinical-stage immunotherapy company developing the next generation of novel T cell therapies for patients suffering from cancer, today reported financial results for the fourth quarter and full year ended December 31, 2018 and provided a corporate update.

"TCR² has achieved important scientific, clinical, and operational milestones over the past year," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. "Although adoptive T cell therapies have made significant progress in the fight against cancer, our TRuC platform has the potential to both improve upon existing options and expand their use. TC-210 has cleared its IND and we have initiated our Phase 1/2 clinical trial, with initial data expected later this year. We also remain on track to submit an IND for TC-110 in the second half of 2019. In February, we successfully completed our initial public offering, a significant step for the Company which further strengthened our financial position."

2018 Corporate Highlights

- Advanced TC-210, TCR²'s lead T cell receptor (TCR) Fusion Construct T cell (TRuC™ T cell) product candidate, to investigational new drug (IND) application submission in December 2018 and IND clearance by the U.S. Food and Drug Administration (FDA) in January 2019. TCR² engineered TC-210 T cells to target and kill mesothelin-expressing cancers while engaging the entire TCR, independent of human leukocyte antigens (HLA). In preclinical studies, TC-210 has demonstrated better anti-tumor activity, longer persistence, and lower cytokine release compared to chimeric antigen receptor (CAR)-T cells engineered with the same mesothelin binder. TCR² initiated a Phase 1/2 clinical trial for TC-210 to treat patients with mesothelin-positive solid tumors, including non-small cell lung cancer (NSCLC), ovarian cancer, malignant pleural/peritoneal mesothelioma, and cholangiocarcinoma. TCR² expects to generate its first clinical data for TC-210 in the second half of 2019.
 - Expanded the TCR² pipeline, initiating IND-enabling studies for TC-110 and TC-220 product candidates, and building next-generation enhancements into the TRuC platform.
 - TC-110 is a CD19 targeted TRuC-T cell product candidate designed to treat patients with CD19-positive B-cell hematological malignancies, including diffuse large B-cell lymphoma (DLBCL), adult acute lymphoblastic leukemia (aALL), follicular lymphoma (FL), and other non-Hodgkin lymphoma (NHL) subtypes. In preclinical studies, TC-110 has shown better anti-tumor activity and persistence compared to CD28 and 4-1BB CAR-T cells engineered with the same CD19 binder, while also exhibiting lower levels of cytokine release.
 - TC-220 is a MUC16 (Mucin 16, Cell Surface Associated)-targeted TRuC-T cell product candidate designed to treat patients with MUC16-positive solid tumors. MUC16 is highly expressed in many solid tumors, including ovarian, pancreatic, gastric, and colorectal cancers. TC-220 has shown strong anti-tumor activity in preclinical models of MUC16-positive ovarian cancers. TCR² plans to file an IND for TC-220 in the first half of 2020.
-

- TCR² is developing several additional tools that may be incorporated into future TRuC product candidates to overcome tumor defense mechanisms, including dual-antigen targeting and strategies to counter the immunosuppressive microenvironment of solid tumors. TCR² is also evaluating multiple proprietary designs for allogeneic, or off the shelf, TRuC-T cells.
- Established semi-automated Good Manufacturing Practice (GMP) manufacturing process. TCR² currently manufactures GMP-grade clinical lots for TC-210 through third-party contractors. In December 2018, TCR² entered into an agreement with Cell and Gene Therapy (CGT) Catapult Limited (Catapult), which will allow TCR² to manufacture TRuC-T cells using its own personnel at CGT Catapult's facility in Stevenage, UK. The TCR² CGT Catapult facility is expected to be operational in the second half of 2019. At full capacity, TCR² estimates this facility would expand its manufacturing capacity to a total of approximately 400 treatments per year.
- Raised \$125 million in an oversubscribed Series B financing round in March 2018. The financing was co-led by 6 Dimensions Capital and Curative Ventures with participation from new investors Redmile and Arrowmark and all of TCR²'s Series A investors.
- Strengthened its management and board in 2018. This included adding Ian Somaiya as Chief Financial Officer, along with Neil Gibson Ph.D. and Andrew Allen M.D., Ph.D. to the Board of Directors.

Recent Developments

- In January 2019, the FDA cleared the IND for TC-210. TCR² initiated its Phase 1/2 trial to treat patients with NSCLC, ovarian cancer, malignant pleural/peritoneal mesothelioma, and cholangiocarcinoma. TCR² expects to generate initial data from the trial in the second half of 2019.
- In February 2019, TCR² 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 and other offering expenses.
- In February 2019, the FDA granted orphan drug designation to TC-210 for the treatment of mesothelioma.
- TCR² recently held a pre-IND meeting with the FDA and remains on track to submit an IND for TC-110 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 TCR²'s TRuC-T cells that express anti-mesothelin TCR fusion proteins, including TC-210.

Anticipated Milestones

TCR² plans to advance its first three TRuC-T cell product candidates into clinical trials by the first half of 2020, while also establishing and expanding its manufacturing capabilities through its collaboration with CGT Catapult.

- **TC-210** - release initial Phase 1 data from the Phase 1/2 trial in 2H 2019.
- **TC-110** - IND submission in 2H 2019.
- **TC-220** - IND submission in 1H 2020.
- **Catapult manufacturing facility** - operational in 2H 2019.

Financial Highlights

- TCR² ended 2018 with \$123.2 million in cash, cash equivalents, and investments compared to \$19.8 million as of December 31, 2017. Net cash from financing activities for the year ended December 31, 2018 was \$123.0 million compared to \$16.2 for the year ended December 31, 2017. Net cash used in operations was \$18.8 million for the year ended December 31, 2018 compared to \$12.0 million for the year ended December 31, 2017.
- Net loss for the year ended December 31, 2018 was \$24.3 million compared to \$13.1 million for the year ended December 31, 2017.
- Research and development expenses were \$19.7 million for the year ended December 31, 2018 compared to \$9.6 million for the year ended December 31, 2017. The increase in R&D expenses is primarily related to increase in headcount and preclinical development of our lead solid tumor product candidate, TC-210.
- General and administrative expenses were \$6.8 million for the year ended December 31, 2018, compared to \$3.6 million for the year ended December 31, 2017. The increase in general and administrative expenses was primarily due to an increase in personnel costs.

Upcoming Events

Members of the TCR² Therapeutics management team are scheduled to present at the following upcoming conferences.

- **Jefferies Immuno-Oncology Cell Therapy Summit:** Alfonso Quintás Cardama, M.D., Chief Medical Officer, will present on Friday, April 5, 2019 at 7:30am in Boston, MA.
 - **4th Annual CAR-T Congress USA:** Robert Hofmeister Ph.D., Chief Scientific Officer, will present on Wednesday, April 17, 2019 at 9:40am in Boston, MA.
-

- **Class of 2018 Biotech IPOs Investor Day:** Ian Somaiya, Chief Financial Officer, will present on Friday, April 26, 2019 at the offices of Davis Polk in New York, NY.
- **BioTrinity 2019:** Gary Menzel, Ph.D., President and CEO, will present on Tuesday, April 30, 2019 in London, UK.

About TCR² Therapeutics

TCR² Therapeutics Inc. is a clinical-stage immunotherapy company developing the next generation of novel T cell therapies for patients suffering from cancer. 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 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 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 TCR²'s plans to submit an IND for TC-110 in the second half of 2019; the generation of clinical data for TC-210 in the second half of 2019; expectations that TCR²'s Catapult facility will be operational in the second half of 2019 and related effects on TCR²'s manufacturing capacity in the future; and TCR²'s plans to advance its first three TRuC product candidates into clinical trials by the first half of 2020.

The express 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, whether TCR²'s cash resources will be sufficient to fund TCR²'s foreseeable and unforeseeable operating expenses and capital expenditure requirements; and other risks set forth under the caption "Risk Factors" in TCR²'s most recent Annual Report on Form 10-K 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.

Media:

Kathy Vincent
(310) 403-8951
kathy@kathyvincent.com

Investors:

Ian Somaiya
Chief Financial Officer
(617) 949-5210
ian.somaiya@tcr2.com

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

	December 31,	
	2018	2017
Assets		
Current assets		
Cash	\$ 47,674	\$ 19,811
Investments	75,493	—
Prepaid expenses and other current assets	2,326	892
Total current assets	125,493	20,703
Property and equipment, net	1,638	1,026
Restricted cash	290	290
Deferred offering costs	2,012	20
Total assets	\$ 129,433	\$ 22,039
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Accounts payable	\$ 2,663	\$ 427
Accrued expenses and other current liabilities	2,802	804
Total current liabilities	5,465	1,231
Other liabilities	434	30
Total liabilities	5,899	1,261
Redeemable convertible preferred stock, \$0.0001 par value		
Series A preferred stock shares 45,000,000 authorized; 44,500,001 shares issued and outstanding at December 31, 2018 and 2017 (liquidation preference of \$49.8 million at December 31, 2018)	72,980	47,102
Series B preferred stock: 62,500,000 and no shares authorized at December 31, 2018 and 2017, respectively; 62,500,000 shares and no shares authorized and outstanding as of December 31, 2018 and 2017, respectively (liquidation value of \$130.9 million at December 31, 2018).	136,250	—
Total redeemable convertible preferred stock	209,230	47,102
Common stock, \$0.0001 par value; 20,988,730 and 13,239,045 shares authorized at December 31, 2018 and 2017, respectively; 914,602 and 612,962 shares issued at December 31, 2018 and 2017, respectively; 726,994 and 435,630 shares outstanding at December 31, 2018 and 2017, respectively.	—	—
Additional paid-in capital	—	—
Accumulated other comprehensive income (loss)	(106)	—
Accumulated deficit	(85,590)	(26,324)
Total stockholders' equity (deficit)	(85,696)	(26,324)
Total liabilities, redeemable preferred stock and stockholders' equity (deficit)	\$ 129,433	\$ 22,039

TCR² THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)
(unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2018	2017	2018	2017
Operating expenses				
Research and development	\$ 6,219	\$ 2,747	\$ 19,673	\$ 9,569
General and administrative	2,222	1,290	6,780	3,611
Total operating expenses	8,441	4,037	26,453	13,180
Loss from operations	(8,441)	(4,037)	(26,453)	(13,180)
Other income, net	751	25	2,202	110
Net loss	(7,690)	(4,012)	(24,251)	(13,070)
Accretion of redeemable convertible preferred stock to redemption value	(3,730)	(522)	(37,298)	(1,794)
Net loss attributable to common stockholders	\$ (11,420)	\$ (4,534)	\$ (61,549)	\$ (14,864)
Per share information				
Net loss per share of common stock, basic and diluted	\$ (16.22)	\$ (11.02)	\$ (98.53)	\$ (39.94)
Weighted average shares outstanding, basic and diluted	703,874	411,289	624,659	372,116

TCR² THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(amounts in thousands)
(unaudited)

	YEARS ENDED DECEMBER 31,	
	2018	2017
Operating activities:		
Net loss	\$ (24,251)	\$ (13,070)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	419	298
Stock-based compensation expense	2,133	408
Loss on fixed asset disposal	2	—
Accretion on investments	(280)	—
Changes in operating assets and liabilities:		
Interest receivable on investments	(390)	—
Prepaid expenses and other current assets	(1,043)	103
Accounts payable	2,224	(101)
Accrued expenses and other liabilities	2,408	347
Cash used in operating activities	(18,778)	(12,015)
Investing activities:		
Purchase of investments	(97,810)	(6,480)
Proceeds from maturity of investments	22,490	14,830
Change in restricted cash	—	(290)
Purchases of equipment	(1,019)	(388)
Cash (used in) provided by investing activities	(76,339)	7,672
Financing activities:		
Proceeds from the sale of Series A preferred stock	—	16,167
Proceeds from the sale of Series B preferred stock	125,000	—
Proceeds from the exercise of stock options	140	44
Deferred offering costs	(1,990)	(20)
Payment of issuance costs	(170)	(28)
Cash provided by financing activities	122,980	16,163
Net increase in cash and cash equivalents	27,863	11,820
Cash and cash equivalents at beginning of year	19,811	7,991
Cash and cash equivalents at end of year	\$ 47,674	\$ 19,811
Supplemental disclosure of noncash financing activities:		
Accretion of redeemable convertible preferred stock to redemption value	\$ 37,298	\$ 1,794
Deferred offering costs included in accounts payable	558	20
Property and equipment additions in accounts payable	14	—
Reclassification of early exercise liability upon vesting of options	10	—

###