

**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): November 1, 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
(IRS Employer
Identification No.)

**100 Binney Street
Suite 710
Cambridge, Massachusetts**
(Address of Principal Executive Offices)

02142
(Zip Code)

Registrant's Telephone Number, Including Area Code: 617 949-5200

(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, \$0.0001 Par Value	TCRR	NASDAQ Global Select Market

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 2.05 Costs Associated with Exit or Disposal Activities.

On November 1, 2021, TCR² Therapeutics Inc (the “Company”) announced a proposal to consolidate its manufacturing operations in the United States. Under the proposal, manufacturing operations at the Company’s facility in Stevenage, United Kingdom (“UK”), would cease by the end of 2021. The Company estimates that this could affect an estimated 34 employees in the UK. In accordance with UK law, the UK-based employees will enter into a consultation period in respect of the proposed plan to close the Stevenage, UK, facility prior to any final decision being made. The Company anticipates that the consultation period will be concluded on or about December 10, 2021.

Should the Company proceed with the proposal, the Company expects to reduce annual operating expenses in 2022 by approximately \$16 million and incur pre-tax restructuring charges in the fourth quarter of 2021, which could include one-time employee severance and termination benefits, facility closure costs, costs to relocate certain equipment and other disposal and restructuring charges of approximately \$4.0 to \$4.5 million.

A copy of the press release announcing the proposed consolidation plan is provided as Exhibit 99.1 of this Current Report, and is incorporated into this Item 2.05 by reference.

Statements contained under this Item 2.05, including Exhibit 99.1, regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements include, but are not limited to, express or implied statements regarding the therapeutic potential of gavo-cel and the Company’s emerging solid tumor pipeline, expectations regarding increased demand for the Company’s product candidate trials, the proposed consolidation of manufacturing in the US and closure of the manufacturing suite in Stevenage, UK, and related costs, expectations regarding manufacturing plans and capabilities, future clinical development and commercialization plans, and the development of the Company’s TRuC-T cells.

Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include, 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 a trial; the possibility that positive results from preclinical studies and correlative studies may not necessarily be predictive of the results of the Company’s planned clinical trials; 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; the Company’s ability to maintain sufficient manufacturing capabilities to support its research, development and commercialization efforts, including the Company’s ability to secure additional manufacturing facilities; whether the Company’s cash resources will be sufficient to fund the Company foreseeable and unforeseeable operating expenses and capital expenditure requirements, the impact of the COVID-19 pandemic on the Company’s ongoing operations; and other risks set forth under the caption “Risk Factors” in the Company’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. All forward-looking statements contained in this presentation speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated November 1, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

TCR² Therapeutics Inc.

Date: November 1, 2021

By: /s/ Mayur (Ian) Somaiya

Mayur (Ian) Somaiya
Chief Financial Officer



TCR² Therapeutics Announces Expansion of U.S. Manufacturing Capacity

- Second clean room at ElevateBio BaseCamp will expand cGMP capacity for clinical trials in 2022
- Future network to focus on TCR² manufacturing center of excellence in Rockville, MD
- Strategy optimizes efficiencies and simplifies regulatory pathway

CAMBRIDGE, Mass., November 1, 2021 - 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, announced today the expansion of its manufacturing capacity by exercising an option on a second clean room at ElevateBio BaseCamp which adds to the buildout of clinical and commercial supply currently underway at its Rockville, MD, facility.

The timing of the additional supply at ElevateBio BaseCamp aligns with an anticipated 2022 increase in demand from the Phase 2 clinical trial of gavo-cel for mesothelin-expressing solid tumors as well as the start of a Phase 1 clinical trial for TC-510, a mesothelin TRuC-T cell enhanced with a PD1xCD28 switch. The long-term focus for TCR² clinical and commercial supply remains on developing the 85,000 square foot Rockville facility as its manufacturing center of excellence in the U.S. In connection with this expansion, TCR² proposes to cease manufacturing activities at the Cell and Gene Therapy Catapult (CGT Catapult) in Stevenage, UK.

“This increase in cGMP manufacturing capacity at ElevateBio BaseCamp will ensure we are able to execute on the gavo-cel Phase 2 trial and the clinical plans for our next-generation TRuC-T cell products,” said Garry Menzel, President and Chief Executive Officer of TCR² Therapeutics. “We are excited by the therapeutic potential of our lead clinical therapy gavo-cel and the emerging solid tumor pipeline reviewed recently at our R&D Day. Our strategy remains focused on continuous innovation providing multiple opportunities to save the lives of cancer patients”.

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. 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 and TCR²’s emerging solid tumor pipeline, expectations regarding increased demand for TCR²’s product candidate trials, the proposed consolidation of manufacturing in the US and closure of the manufacturing suite in Stevenage, UK and related costs, expectations regarding manufacturing plans and capabilities, future clinical development and commercialization plans, and the development of TCR²’s TRuC-T cells.

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.

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