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 Act of 1934

Date of Report (Date of earliest event reported):
October 25, 2021

TCR2 THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware 001-38811 47-4152751

(State or other jurisdiction of incorporation or organization)

(Commission File Number)

(I.R.S. Employer Identification Number)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant und	er any of
the following provisions:	

- □ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- $\ \square$ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant t	o Rule 14d-2(b) under the Exchange	e Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant t	o Rule 13e-4(c) under the Exchange	e Act (17 CFR 240.13d-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
of this chapter) or Rule 12b-2 of the Securities Exchar	10E ACLUL 1954 (9740.170-7 OFINS (
	.goc. c c	Emerging growth company 🗵
If an emerging growth company, indicate by check ma with any new or revised financial accounting standards	rk if the registrant has elected not to	Emerging growth company use the extended transition period for complying
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Item 8.01 Other Events.

On October 25, 2021, TCR² Therapeutics Inc. (the "Company") issued a press release announcing a clinical trial collaboration agreement with Bristol Myers Squibb to evaluate gavo-cel in combination with Opdivo® (nivolumab) and Yervoy® (ipilimumab) in its planned Phase 2 clinical trial in treatment refractory mesothelin-expressing solid tumors. A copy of the press release titled "TCR² Therapeutics Announces Clinical Trial Collaboration Agreement with Bristol Myers Squibb to Evaluate Gavo-cel in Combination with Opdivo and Yervoy in Mesothelin-Expressing Solid Tumors" is being filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Statements contained under this Item 8.01, 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 as a monotherapy or in combination with immune checkpoint inhibitors, timing for interim updates for the gavo-cel clinical trial, expectations regarding manufacturing plans and capabilities, future clinical development and commercialization 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.

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 TCR2'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-O 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

Exhibit No.	Description
99.1	Press release issued by TCR2 Therapeutics Inc. on October 25, 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 hereunto duly authorized.

TCR² THERAPEUTICS INC.

Ву:

/s/ Mayur (Ian) Somaiya

Name:

Mayur (Ian) Somaiya

Title:

Chief Financial Officer

Date: October 25, 2021

TCR² Therapeutics Announces Clinical Trial Collaboration Agreement with Bristol Myers Squibb to Evaluate Gavo-cel in Combination with Opdivo® and Yervoy® in Mesothelin-Expressing Solid Tumors

CAMBRIDGE, Mass., October 25, 2021 - TCR² Therapeutics Inc. (Nasdaq: TCRR), a clinical-stage cell therapy company with a pipeline of novel T cell therapies for patients suffering from solid tumors, today announced a clinical trial collaboration agreement with Bristol Myers Squibb (NYSE: BMY) to evaluate gavo-cel in combination with Opdivo® (nivolumab) and Yervoy® (ipilimumab) in its planned Phase 2 clinical trial in treatment refractory mesothelin-expressing solid tumors. The primary objective of the Phase 2 trial is to evaluate the efficacy of gavo-cel in patients with unresectable, metastatic or recurrent mesothelin-expressing cancers including non-small cell lung cancer (NSCLC), ovarian cancer, malignant pleural/peritoneal mesothelioma (MPM) and cholangiocarcinoma. TCR² is sponsoring the Phase 2 trial.

"We are very pleased to establish a collaboration agreement with Bristol Myers Squibb for our Phase 2 clinical trial as this enables us to evaluate the potential synergy between gavo-cel and immune checkpoint inhibitors," said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. "The new standard of care established by *Opdivo* in difficult-to-treat diseases is important for cancer patients around the world, including the recent approval of the combination of *Opdivo* and *Yervoy* as first-line treatment for adult patients with unresectable malignant pleural mesothelioma. We look forward to determining whether gavo-cel can provide additional clinical benefit to these patients."

The planned Phase 2 clinical trial will evaluate the antitumor activity and better characterize the safety of gavo-cel at the selected recommended Phase 2 dose (RP2D). Patients will receive gavo-cel at the RP2D and will be enrolled according to their cancer diagnosis to four distinct cohorts: NSCLC, ovarian cancer, MPM and cholangiocarcinoma. Patients with NSCLC, ovarian cancer, or cholangiocarcinoma will receive the combination of gavo-cel and *Opdivo*. Patients with MPM will be treated in three cohorts: the first will administer gavo-cel as a single agent, the second will treat patients with both gavo-cel and *Opdivo*, and the third will treat patients with gavo-cel, *Opdivo* and *Yervoy*.

Opdivo® and Yervoy® are trademarks of Bristol-Myers Squibb Company.

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 as a monotherapy or in combination with immune checkpoint inhibitors, timing for interim updates for the gavo-cel clinical trial, expectations regarding manufacturing plans and capabilities, future clinical development and commercialization 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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