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) January 23, 2023

TSCAN THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40603**	**82-5282075**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

830 Winter Street, Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (857) 399-9500

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	**Trade Symbol(s)**	**Name of each exchange on which registered**
Voting Common Stock, $0.0001 par value per share	TCRX	The Nasdaq Global 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 8.01 Other Events.

On January 23, 2023, TScan Therapeutics, Inc. ("TScan" or the "Company"), issued a press release announcing that the U.S. Food and Drug Administration has cleared its investigational new drug ("IND") applications to evaluate T-Plex, TSC-204-A0201 and TSC-204-C0702. T-Plex will now serve as the primary IND for TScan's solid tumor program, enabling customized combinations of T cell receptor-engineered T cell therapies to be administered to patients based on targets and HLAs expressed in their tumors. The press release also announced that TScan also filed secondary INDs for two initial TCR-T products, TSC-204-A0201 and TSC-204-C0702, that target melanoma-associated antigen 1 (MAGE-A1) on HLA types A*02:01 and C*07:02. MAGE-A1 is a cancer-associated antigen overexpressed in 45% of head and neck cancers and 50% of melanoma, cervical, and non-small cell lung cancers. With these INDs cleared, the Company announced that it is now working to open a multicenter Phase 1 clinical trial to establish the safety, preliminary efficacy, and feasibility of repeat dosing of multiplexed TCR-T.

The full text of the press release issued in connection with the announcement is filed as Exhibit 99.1 on this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed as part of this report:

Exhibit Number	Description
99.1	Press release, dated January 23, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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.

TScan Therapeutics, Inc.

Date: January 23, 2023

By: /s/ Brian Silver
Brian Silver
Chief Financial Officer

TScan Therapeutics Announces FDA Clearance of Three Investigational New Drug Applications for the Treatment of Solid Tumors

Primary IND for solid tumor program, T-Plex, supports simultaneous use of multiple TCRs to create customized, multiplexed TCR-T cell therapies based on target and HLA expression

*INDs for TSC-204-A0201 and TSC-204-C0702 introduce the first two TCRs into TScan's ImmunoBank, targeting MAGE-A1 on HLA types A*02:01 and C*07:02, respectively*

WALTHAM, Mass., Jan. 23, 2023 — TScan Therapeutics, Inc. (Nasdaq: TCRX), a clinical-stage biopharmaceutical company focused on the development of T cell receptor (TCR)-engineered T cell therapies (TCR-T) for the treatment of patients with cancer, today announced that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) applications for T-Plex, TSC-204-A0201, and TSC-204-C0702.

T-Plex will now serve as the primary IND for TScan's solid tumor program, enabling customized combinations of TCR-Ts to be administered to patients based on the targets and HLAs expressed in their tumors. The specific TCRs for each patient will be chosen from the Company's ImmunoBank, consisting of high-affinity, naturally occurring TCRs that recognize a variety of prevalent cancer-specific targets and are associated with various common HLA types. Each unique TCR-T will be filed as a secondary IND and will reference the primary T-Plex IND.

In addition to the T-Plex IND, TScan filed secondary INDs for two initial TCR-T products, TSC-204-A0201 and TSC-204-C0702, that target melanoma-associated antigen 1 (MAGE-A1) on HLA types A*02:01 and C*07:02. MAGE-A1 is a cancer-associated antigen overexpressed in 45% of head and neck cancers and 50% of melanoma, cervical, and non-small cell lung cancers. TScan believes that TSC-204-C0702 is the first clinical program in MAGE-A1 for an HLA type other than A*02:01. With these INDs cleared, TScan is now working to open a multicenter Phase 1 clinical trial to establish the safety, preliminary efficacy, and feasibility of repeat dosing of multiplexed TCR-T. The trial will include patients with non-small cell lung cancer, melanoma, head and neck cancer, ovarian cancer, and cervical cancer.

"With the clearance of these three INDs, we believe we are the only company in the cell therapy field to have a clear clinical and regulatory path to develop multiplexed TCR-T cell therapy, which we see as critical for achieving durable responses in patients with solid tumors by overcoming resistance due to target or HLA loss. We will continue to rapidly build out our ImmunoBank, allowing us to deliver customized treatments tailored to each patient's tumor biology," said Gavin MacBeath, Ph.D., Chief Scientific and Operations Officer. "We are now engaged in study start-up activities and look forward to sharing initial clinical data for the most advanced TCRs in this program by the end of 2023."

David P. Southwell, President and Chief Executive Officer continued: "Today marks the first three IND clearances for our solid tumor program and further validates the use of our proprietary platform to identify therapeutic TCRs suitable for clinical development. With the FDA clearance of T-Plex, along with two MAGE-targeting TCRs, we are now one step closer to bringing bespoke cell therapies to patients. We are continuing to build our ImmunoBank, with four more IND filings anticipated in 2023."

In the Phase 1 trial design, each TCR-T will initially be evaluated as singleplex therapy at two successive dose levels. Once single agent safety is established, each TCR becomes eligible for combination with any other TCR that has passed this threshold. The protocol has an interval 3+3 design, potentially allowing for a rapid path to multiplexing. The trial design also features a screening protocol, which pre-identifies patients whose tumors have a combination of targets and HLAs that would qualify them for the interventional study. The screening protocol is expected to initiate in Q2 2023.

About TScan Therapeutics, Inc.

TScan is a clinical-stage biopharmaceutical company focused on the development of T cell receptor (TCR)-engineered T cell therapies (TCR-T) for the treatment of patients with cancer. The Company's lead TCR-T therapy candidates, TSC-100 and TSC-101, are in development for the treatment of patients with hematologic malignancies to eliminate residual disease and prevent relapse after allogeneic hematopoietic cell transplantation. The Company is also developing multiplexed TCR-T therapy candidates for the treatment of various solid tumors. The Company has developed and continues to build its ImmunoBank, the Company's repository of therapeutic TCRs that recognize diverse targets and are associated with multiple HLA types, to provide customized multiplexed TCR-T therapies for patients with a variety of solid tumors.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, express or implied statements regarding the Company's plans, progress, and timing relating to the Company's solid tumor programs and the presentation of data, the Company's current and future research and development plans or expectations, the structure, timing and success of the Company's planned preclinical development, submission of INDs, and clinical trials, the potential benefits of any of the Company's proprietary platforms, multiplexing, or current or future product candidates in treating patients, and the Company's goals and strategy. TScan intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as, but not limited to, "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan," "on track," or similar expressions or the negative of those terms. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions, and uncertainties. The express or implied forward-looking statements included in this release are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation: the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of TScan's TCR-T therapy candidates; TScan's expectations regarding its preclinical studies being predictive of clinical trial results; the timing of the initiation, progress and expected results of TScan's preclinical studies, clinical trials and its research and development programs; TScan's plans relating to developing and commercializing its TCR-T therapy candidates, if approved, including sales strategy; estimates of the size of the addressable market for TScan's TCR-T therapy candidates; TScan's manufacturing capabilities and the scalable nature of its manufacturing process; TScan's estimates regarding expenses, future milestone payments and revenue, capital requirements and needs for additional financing; TScan's expectations regarding competition; TScan's anticipated growth strategies; TScan's ability to attract or retain key personnel; TScan's ability to establish and maintain development partnerships and collaborations; TScan's expectations regarding federal, state and foreign regulatory requirements; TScan's ability to obtain and maintain intellectual property protection for its proprietary platform technology and our product candidates; the sufficiency of TScan's existing capital resources to fund its future

operating expenses and capital expenditure requirements; and the effect of the COVID-19 pandemic, including mitigation efforts and political, economic, legal and social effects, on any of the foregoing or other aspects of TScan's business or operations; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of TScan's most recent Annual Report on Form 10-K and any other filings that TScan has made or may make with the SEC in the future. Any forward-looking statements contained in this release represent TScan's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, TScan explicitly disclaims any obligation to update any forward-looking statements.

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