

**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)

March 08, 2023

TSCAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40603
(Commission File Number)

82-5282075
(IRS Employer
Identification No.)

830 Winter Street
Waltham, Massachusetts
(Address of principal executive offices)

02451
(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	Trading Symbol(s)	Name of each exchange on which registered
Voting Common Stock, par value \$0.0001 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 2.02 Results of Operations and Financial Condition.

On March 8, 2023, TScan Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall neither be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, as amended, or the Exchange Act, regardless of any general incorporation language in such filings, unless expressly incorporated by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued by TScan Therapeutics, Inc., dated March 8, 2023.
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.

TScan Therapeutics, Inc.

Date: March 8, 2023

By: /s/ Brian Silver

Brian Silver
Chief Financial Officer



TScan Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Highlights Upcoming Milestones

Phase 1 umbrella trial for TSC-100 and TSC-101 in hematologic malignancies on track to enroll patients into each of the three study arms and provide a clinical update including safety and biomarker data by mid-year 2023

Clearance of primary IND (T-Plex) in addition to two INDs for lead TCR-Ts supports concomitant use of multiple TCRs for solid tumor trial; initial data for most advanced TCRs anticipated by year-end 2023

Ended 2022 with cash and cash equivalents of \$120.0 million, funding operations into 2Q 2024

WALTHAM, Mass., Mar. 8, 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 reported financial results for the three months and full year ended December 31, 2022, and highlighted upcoming anticipated milestones.

“This will be a pivotal year for TScan. We expect to have patients enrolled in all three arms of our hematologic malignancies program and plan to provide a clinical update by mid-year,” said David P. Southwell, President and Chief Executive Officer. “Our solid tumor program is also advancing to the clinic this year. TScan is the first company to launch a trial that will treat cancer patients with multiplexed TCR-T cell therapies matched to the HLA and target profile of their tumors. This approach should help overcome target and HLA loss, which are known mechanisms of resistance. Following the clearance of the first three INDs for our solid tumor program in January, including our T-Plex IND enabling the combination of different TCRs, we are rapidly populating our ImmunoBank to enable a broad range of multiplexed T cell therapies for patients. We plan to file INDs for four additional solid tumor TCRs throughout the year. With \$120 million of cash on hand, we are well capitalized to execute on these upcoming milestones.”

“We are now actively recruiting patients into our hematologic malignancies program,” commented Debora Barton, M.D., Chief Medical Officer. “Several sites are currently recruiting patients, with additional sites to be activated throughout this year. We expect that we will reach the recommended Phase 2 dose for TSC-100 and TSC-101 and report further clinical safety and biomarker data for the program by the end of 2023. Many of the clinical sites enrolling patients in our hematologic malignancies program are planning to join our solid tumor study. That study is planned to begin enrolling patients into the screening protocol by the middle of this year, with patient dosing expected to commence in the third quarter. We plan to share initial safety and biomarker data for single agent TCRs by the end of 2023, with initial multiplexing data expected in the first half of 2024.”

“TScan’s TCR-T cell products have been designed to improve upon first-generation TCR-T in two important ways: by increasing depth of response and by extending duration of response,” said Gavin MacBeath, Ph.D., Chief Scientific and Operations Officer. “Our non-viral, in-house manufacturing platform allows us to add enhancements to our TCRs, including CD8 α / β to

increase depth of response by enlisting helper T cells, and a dominant negative form of TGFβRII to overcome inhibition of T cells by TGFβ in the hostile tumor microenvironment. To address antigen heterogeneity and HLA loss, our recently approved T-Plex IND allows us to multiplex our enhanced TCR-Ts across targets and HLA types at the same time, bringing us closer to our goal of providing customized TCR-T therapy to treat patients with a wide variety of solid tumor malignancies.”

Recent Corporate Highlights

- TScan filed three investigational new drug (IND) applications with the U.S. Food and Drug Administration (FDA) for its solid tumor program in December 2022. The IND applications for T-Plex, TSC-204-A0201, and TSC-204-C0702 have now been cleared by the FDA. T-Plex will serve as the primary IND for TScan’s solid tumor program, enabling customized mixtures of TCR-Ts to be administered to patients based on tumor antigen positivity and HLA expression. Along with T-Plex, the FDA has approved secondary INDs for two TCR-T products, TSC-204-A0201 and TSC-204-C0702, that target melanoma-associated antigen 1 (MAGE-A1) presented on HLA A*02:01 and C*07:02, respectively. MAGE-A1 is a validated 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 TCR to enter clinical trials for an epitope of MAGE-A1 presented on an HLA type other than A*02:01.
- In December 2022, the Company presented a poster on the clinical trial design and trial in progress for the Phase 1 umbrella trial of TSC-100 and TSC-101 to treat residual leukemia and prevent relapse after hematopoietic cell transplant (HCT) at the 64th American Society of Hematology (ASH) Annual Meeting 2022.
- In November 2022, the Company presented two posters at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting:
 - Discovery of PRAME-specific TCR-T cell therapy candidates for the treatment of solid tumors, presented by Mollie Jurewicz, Ph.D.
 - Multiplexed TCR-T cell therapy targeting MAGE-A1 and PRAME enhances the activity of adoptive T cell therapy in pre-clinical models, presented by Antoine Boudot, Ph.D.
- During the fourth quarter of 2022, TScan was named the best mid-sized biotechnology company in the Top Places to Work for 2022 by *The Boston Globe*. Top Places to Work recognizes the most admired workplaces in the state voted on by the people who know them best – their employees. The survey measures employee opinions about their Company’s direction, execution, connection, management, work, pay and benefits, and engagement.

Upcoming Anticipated Milestones

Hematologic Malignancies Program:

- Expects to enroll patients in all three arms in the Phase 1 umbrella trial (NCT05473910) for TSC-100 and TSC-101 and start reporting preliminary safety and biomarker data mid-year 2023.
 - Expects to reach the recommended Phase 2 dose for TSC-100 and TSC-101 and report interim clinical data for the program by the end of 2023.
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The Company expects to report prevention of relapse data in 2024.

Solid Tumor Program:

- Anticipate further expansion of the ImmunoBank by filing INDs for four TCRs throughout 2023.
- Anticipate sharing preliminary safety and biomarker data for the most advanced TCRs by the end of 2023.
- The Company expects to report initial multiplex therapy data for its first combination of TCRs under T-Plex in the first half of 2024.

Fourth Quarter 2022 Financial Results

Revenue for the three months ended December 31, 2022, was \$3.1 million, compared to \$2.9 million for the three months ended December 31, 2021 (2021 Quarter). This increase is due to the timing of research activities related to our target discovery collaboration with Novartis (the "Novartis Agreement").

Research and development expenses for the three months ended December 31, 2022, were \$15.6 million, compared to \$12.6 million for the 2021 Quarter. The increase of \$3.0 million was primarily driven by an increase in personnel expense, expansion of leased facilities, and preclinical activities to support solid tumors, and Phase 1 study start-up activities for TSC-100 and TSC-101.

General and administrative expenses for the three months ended December 31, 2022, were \$6.1 million, compared to \$4.4 million for the 2021 Quarter. The increase of \$1.7 million in general and administrative expenses was primarily driven by increased personnel and facilities related costs to support the progress of the Company into the clinic.

For the three months ended December 31, 2022, TScan Therapeutics reported a net loss of \$18.7 million, compared to a net loss of \$14.2 million for the 2021 Quarter.

Full Year 2022 Financial Results

As of December 31, 2022, TScan Therapeutics had cash and cash equivalents of \$120.0 million excluding \$5.0 million of restricted cash. Based on current operating plans, the Company believes that existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the second quarter of 2024.

Revenue for the year ended December 31, 2022, was \$13.5 million, compared to \$10.1 million for the year ended December 31, 2021 (2021 Period). This increase is due to the timing of research activities related to the Novartis Agreement.

Research and development expenses for the year ended December 31, 2022, were \$59.8 million, compared to \$45.0 million for the 2021 Period. The increase of \$14.8 million was primarily driven by an increase in personnel expense, expansion of leased facilities, preclinical activities to support solid tumors, and Phase 1 study start-up activities for TSC-100 and TSC-101.

General and administrative expenses for the year ended December 31, 2022, were \$20.4 million, compared to \$13.8 million for the 2021 Period. The increase of \$6.5 million in general and administrative expenses was primarily driven by increased personnel and facilities related costs to support the progress of the company into the clinic.

For the year ended December 31, 2022, TScan Therapeutics reported a net loss of \$66.2 million, compared to a net loss of \$48.6 million for the 2021 Period.

As of December 31, 2022, the Company had issued and outstanding a combined total of 24,225,954 shares of voting common stock and non-voting common stock.

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 clinical development for the treatment of patients with hematologic malignancies to eliminate residual disease and prevent relapse after allogeneic hematopoietic cell transplantation. The Company's multiplexed TCR-T therapy candidates are in clinical development for the treatment of various solid tumors. To expand the addressable patient population in its ongoing solid tumor trial, the Company continues to build its ImmunoBank, a repository of therapeutic TCRs that recognize diverse targets and are associated with multiple HLA types that will allow the Company to provide TCRs selected to address the specific antigens presented by each patient's tumor.

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, the Company's ability to fund its operating expenses and capital expenditure requirements with its existing cash and cash equivalents, and the Company's goals and strategy, focus, and anticipated financial performance. 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," "advance," "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; TScan's recently approved INDs being indicative or predictive of bringing TScan closer to its goal of providing customized TCR-T therapies to treat patients with cancer; the timing of the launch, initiation, progress and expected results and announcements of TScan's preclinical studies, clinical trials and its research and development programs; TScan's timeline regarding its filing of INDs for its TCRs throughout the year, TScan's ability to enroll patients for its clinical trials within its expected timeline, 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 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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TScan Therapeutics, Inc.
Condensed Consolidated Balance Sheet Data
(unaudited, in thousands, except share amount)

	December 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	\$ 120,027	\$ 161,405
Other assets	79,064	26,702
Total assets	\$ 199,091	\$ 188,107
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Total liabilities	\$ 99,657	\$ 27,329
Total stockholders' equity (deficit)	99,434	160,778
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 199,091	\$ 188,107
Common stock outstanding as of December 31, 2021	24,225,954	

TScan Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(unaudited, in thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Revenue				
Collaboration and license revenue	\$ 3,096	\$ 2,854	\$ 13,535	\$ 10,141
Operating expenses:				
Research and development	15,604	12,608	59,819	44,954
General and administrative	6,140	4,448	20,352	13,828
Total operating expenses	21,744	17,056	80,171	58,782
Loss from operations	(18,648)	(14,202)	(66,636)	(48,641)
Other income	900	2	1,591	16
Interest expense	(975)	-	(1,176)	-
Net loss	\$ (18,723)	\$ (14,200)	\$ (66,221)	\$ (48,625)
Net loss per share, basic and diluted	\$ (0.78)	\$ (0.60)	\$ (2.75)	\$ (4.17)
Weighted average common shares outstanding—basic and diluted	24,077,857	23,829,705	24,048,267	11,662,672

