# **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)

August 10, 2023

# **TSCAN THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

830 Winter Street Waltham, Massachusetts

(Address of principal executive offices)

001-40603 (Commission File Number)

82-5282075 (IRS Employer Identification No.)

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:

	Trading			
Title of each class 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  $\boxtimes$ 

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.  $\Box$ 

#### Item 2.02 Results of Operations and Financial Condition.

On August 10, 2023, TScan Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 2023. 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 August 10, 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: August 10, 2023

By: /s/ Gavin MacBeath

Gavin MacBeath Chief Executive Officer



# TScan Therapeutics Reports Second Quarter 2023 Financial Results and Provides Corporate Update

Presented preliminary Phase 1 clinical data from heme malignancies trial at the ASGCT 26<sup>th</sup> Annual Meeting; expect to reach recommended Phase 2 dose for two TCR-T therapy product candidates and report interim data by year-end 2023

Announced FDA clearance of fourth IND for solid tumor program – TSC-200-A0201 targeting HPV16

Closed underwritten public offering with net proceeds of approximately \$134.7 million

Ended 2Q 2023 with cash and cash equivalents of \$208.8 million, which along with \$30 million proceeds from Amgen, will fund the Company into 2026

**WALTHAM, Mass., Aug 10, 2023** -- TScan Therapeutics, Inc. (Nasdaq: TCRX), a clinical-stage biopharmaceutical company focused on the development of T cell receptor-engineered T cell therapies (TCR-Ts) for the treatment of patients with cancer, today reported financial results and provided a corporate update for the second quarter ended June 30, 2023.

"The success of the second quarter has been a testament to the hard work here at TScan over the last six months," said Gavin MacBeath, Ph.D., Chief Executive Officer. "We are encouraged by the initial clinical data from our heme malignancies program and look forward to reaching the recommended Phase 2 dose for both TSC-100 and TSC-101 and providing a more extensive update by the end of this year. We continue to successfully enroll and treat patients in the dose escalation portion of the Phase 1 study and have not observed any dose limiting toxicities to date. Both TCR-T product candidates are now proceeding through dose level 2. With regards to the solid tumor program, we continue to focus our efforts on populating the ImmunoBank with TCR-Ts that address different targets and diverse HLA types to enable tailored, multiplexed TCR-T therapies. Following the close of an underwritten public offering in June, we are well capitalized to execute on upcoming anticipated milestones into 2026, by which time we expect to report data for both clinical programs."

#### **Corporate Highlights**

In May 2023, the Company presented preliminary data from its ongoing multi-arm Phase 1 clinical trial evaluating TSC-100 and TSC-101, two different TCR-T cell therapy product candidates that are designed to treat residual disease and prevent relapse following hematopoietic cell transplantation in patients with acute myeloid leukemia (AML), myelodysplastic syndromes (MDS), or acute lymphocytic leukemia (ALL). Data were presented at the American Society of Gene & Cell Therapy (ASGCT) 26<sup>th</sup> Annual Meeting 2023. Both TSC-100 and TSC-101 showed markers of T cell activation and proliferation in patients, with no dose limiting toxicities. The Company also reported donor chimerism data for three patients. Two medium-risk MDS patients in the control arm showed incomplete donor chimerism, whereas the high-risk MDS patient in the TSC-101 arm showed complete donor chimerism within three weeks of receiving the

engineered TCR-T cell product. The study is now advancing to dose level 2 in both the TSC-100 and TSC-101 arms. TScan remains on track to reach the recommended Phase 2 dose for both products and report interim clinical data for the program by the end of 2023.

- The Company recently announced the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application for TSC-200-A0201, a TCR-T targeting the E7 protein of human papillomavirus 16 (HPV16). TSC-200-A0201 is the third TCR-T cleared to initiate clinical development in the Company's solid tumor program. TSC-204-A0201 and TSC-204-C0702, which target MAGE-A1 presented on HLA types A\*02:01 and C\*07:02, respectively, were cleared earlier this year. TScan is on-track to initiate clinical development of all three TCR-T candidates in a multi-arm Phase 1 basket study in the second half of 2023. The clinical trial, which has received clearance from the FDA, is designed to assess the safety and efficacy of each candidate individually at two different dose levels, and then to assess custom combinations of TCR-Ts at dose levels 3 and 4 in patients that qualify to receive more than one therapeutic candidate. TScan plans to file INDs for three additional TCR-T candidates by year end, including a TCR-T that targets the tumor-associated antigen PRAME. Upon FDA clearance, these candidates will be introduced into the ongoing clinical trial, thereby increasing patient eligibility for multiplexed TCR-T cell therapy.
- During the second quarter, TScan announced the closing of an underwritten public offering with net proceeds of approximately \$134.7 million. The Company intends to use the proceeds for general corporate purposes. Following this offering, the Company expects that its existing cash and cash equivalents, along with proceeds from the collaboration agreement with Amgen, will fund its operating expenses and capital expenditure requirements into 2026.
- In June 2023, TScan presented a trial in progress poster for its solid tumor program at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. A copy of the poster can be found on the "Publications" section of the Company's website at www.tscan.com.

#### **Upcoming Anticipated Milestones**

#### Heme Malignancies Program:

- Expects to reach the recommended Phase 2 dose for both TSC-100 and TSC-101 and report interim clinical data for the program by the end of 2023.
- Plans to complete Phase 1 dosing and report prevention of relapse data in 2024.

#### Solid Tumor Program:

- Anticipates further expansion of the ImmunoBank with the recent filing of an IND for TSC-203-A0201, an HLA-A\*02:01-restricted TCR targeting PRAME, and IND filings for two additional TCRs by year-end.
- Plans to initiate Phase 1 solid tumor clinical study in the second half of 2023 and anticipates sharing preliminary data by the end of 2023.

• Expects to report initial multiplexed therapy data for its first combinations of TCR-Ts under T-Plex, as well as response data for singleplex cohorts, in 2024.

#### Second Quarter 2023 Financial Results

As of June 30, 2023, TScan Therapeutics had cash and cash equivalents of \$208.8 million, excluding \$5.0 million of restricted cash. Based on current operating plans, the Company believes that existing cash and cash equivalents, along with proceeds from the collaboration with Amgen, will be sufficient to fund its operating expenses and capital expenditure requirements into 2026.

Revenue for the second quarter ended June 30, 2023, was \$3.1 million, compared to \$4.1 million for the second quarter ended June 30, 2022 (2022 Quarter). This decrease is primarily due to timing of research activities related to the collaboration agreement with Amgen in the second quarter of 2023 versus timing of research activities related to a collaboration and license agreement with Novartis Institutes for Biomedical Research, Inc. in the 2022 Quarter.

Research and development expenses for the second quarter ended June 30, 2023, were \$21.2 million, compared to \$14.5 million for the 2022 Quarter. The increase of \$6.7 million was primarily driven by increased costs associated with clinical trial start-up fees and patient enrollment, increased personnel costs, and expansion of facilities.

General and administrative expenses for the second quarter ended June 30, 2023, were \$6.5 million, compared to \$4.8 million for the 2022 Quarter. The increase of \$1.7 million in general and administrative expenses was primarily driven by increased legal fees related to transactions entered into during the second quarter of 2023.

For the second quarter ended June 30, 2023, TScan Therapeutics reported a net loss of \$24.0 million, compared to a net loss of \$15.1 million for the 2022 Quarter.

As of June 30, 2023, the Company had issued and outstanding shares of 47,818,766, which consists of 43,542,178 shares of voting common stock and 4,276,588 shares of non-voting common stock, and outstanding pre-funded warrants to purchase 47,010,526 shares of common stock at an exercise price of \$0.0001 per share.

#### 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: TScan's views regarding its initial clinical data from the heme malignancies program; TScan's expected timeline for completing Phase 1 dose escalation, reaching the recommended Phase 2 dose and providing updates on its clinical program; the anticipation of further expansion of TScan's ImmunoBank throughout 2023; the plans regarding initiation of clinical trials; the anticipation of release of preliminary data by the end of 2023; 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 execute on upcoming anticipated milestones into 2026; 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.

### Contacts

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## TScan Therapeutics, Inc. Condensed Consolidated Balance Sheet Data (unaudited, in thousands, except share amount)

	June 30, 2023		December 31, 2022	
Assets				
Cash and cash equivalents	\$ 208,842	\$	120,027	
Other assets	108,081		79,064	
Total assets	\$ 316,923	\$	199,091	
Liabilities and Stockholders' Equity				
Total liabilities	\$ 126,316	\$	99,657	
Total stockholders' equity	190,607		99,434	
Total liabilities and stockholders' deficit	\$ 316,923	\$	199,091	
Common stock outstanding as of June 30, 2023	47,818,766			

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

	Г	Three Months Ended June 30,			
		2023		2022	
Revenue					
Collaboration and license revenue	\$	3,148	\$	4,056	
Operating expenses:					
Research and development		21,227		14,494	
General and administrative		6,531		4,808	
Total operating expenses		27,758		19,302	
Loss from operations		(24,610)		(15,246)	
Interest and other income, net		1,534		149	
Interest expense		(969)		-	
Net loss	\$	(24,045)	\$	(15,097)	
Net loss per share, basic and diluted	\$	(0.51)	\$	(0.63)	
Weighted average common shares outstanding—basic and diluted		47,208,664		24,063,677	