

**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 10, 2021

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 02451
(Address of principal executive offices, including zip code)

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

N/A
(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 (see General Instruction A.2):

- 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 November 10, 2021, TScan Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not 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, and shall not be deemed incorporated by reference in any filing made by the Company 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.

Exhibit No.	Description
99.1	Press Release dated November 10, 2021.
EX-104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: November 9, 2021

TScan Therapeutics, Inc.

By: /s/ Brian Silver

Brian Silver

Chief Financial Officer

TScan Therapeutics Reports Third Quarter 2021 Financial Results and Highlights Recent Company Progress

IND Submissions Expected in Fourth Quarter 2021 for Lead Liquid Tumor TCR-T Therapy Candidates TSC-100 and TSC-101

Lead TCR Identified for TSC-200 Solid-tumor Program Targeting HPV16; TCR Advancing into IND-Enabling Activities with IND Submission Planned for Second Half of 2022

*New Solid Tumor Program, TSC-204, Established Based on a TCR Targeting an HLA-C*07:02 Epitope of MAGE-A1*

WALTHAM, Mass., November 10, 2021 -- TScan Therapeutics, Inc. (Nasdaq: TCRX), a biopharmaceutical company focused on the development of T-cell receptor (TCR) engineered T cell (TCR-T) therapies for the treatment of patients with cancer, today reported financial results for the quarter ended September 30, 2021, highlighted recent program progress, and outlined key upcoming expected milestones.

“Throughout the third quarter of 2021, we’ve continued to execute on our long-term goals of advancing transformational TCR-T therapy candidates and expect to file IND applications for our lead liquid tumor candidates TSC-100 and TSC-101 by the end of the year,” said David Southwell, President and Chief Executive Officer. “We look forward to sharing additional details on our liquid tumor program at the American Society of Hematology Annual Meeting and Exposition. We also made significant progress across our solid tumor pipeline, particularly the advancement of TSC-200 into IND-enabling studies and the launch of a new TCR program based on the discovery of a novel epitope on the validated solid tumor target MAGE-A1.”

Third Quarter 2021 and Recent Business Highlights

- TScan recently announced that two abstracts related to lead liquid tumor TCR-T therapy candidates TSC-100 and TSC-101 have been accepted for poster presentations at the upcoming American Society of Hematology (ASH) Annual Meeting and Exposition being held from December 11-14, 2021.
 - During the third quarter, TScan advanced a lead TCR-T therapy candidate for its TSC-200 program for HPV16 into investigational new drug (IND)-enabling activities and plans to submit an IND for this program in the second half of 2022. HPV is a well validated cancer target found in HPV-positive tumors, including many cases of head & neck and cervical cancers. Using its proprietary ReceptorScan and TargetScan platforms, TScan screened over half a billion T cells from a variety of human donors to identify a naturally occurring, ultra-high affinity TCR that recognizes an HLA-A*02:01-restricted epitope derived from the E7 protein of HPV16. Previously, clinical data from the National Cancer Institute (NCI) demonstrated a favorable safety and efficacy profile for an HPV TCR. TScan intends to build on the positive NCI results by developing an enhanced autologous TCR-T therapy using its T-Integrate cell manufacturing platform and by multiplexing its HPV TCR with additional TCRs in its TSC-2xx series of cell therapy candidates. TScan has used the large cargo capacity of T-Integrate to include in the TSC-200 construct features that enable engineering of both cytotoxic and helper T cells and features designed to help confer resistance to the immunosuppressive micro-environment of solid tumors.
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- TScan has recently discovered a novel HLA-C*07:02-restricted epitope encoded by the well-known cancer/testis gene MAGE-A1, using its TargetScan platform. This cancer-specific gene is frequently overexpressed in a wide variety of solid tumors. In the U.S., the target is expressed in as many as 45% of head & neck cancer patients, 50% of melanoma patients, 50% of cervical cancer patients and 50% of non-small cell lung cancer patients. The TCR that recognizes this novel epitope was isolated from a patient with head & neck cancer who exhibited an exceptional response to immune checkpoint inhibitor therapy. TScan has launched a new program, TSC-204, that will include multiple TCRs for different HLA-restricted epitopes on this same protein. TScan believes that it is the only company with a disclosed TCR program in MAGE-A1 for HLA types other than A*02:01. The Company has now advanced TSC-204 into lead TCR-T therapy candidate optimization.
- The Company expanded its management team with the appointments of Zoran Zdraveski, J.D., Ph.D., as Chief Legal Officer, and Heather Savelle as Vice President, Investor Relations.
- In July 2021, TScan completed its initial public offering, raising \$100 million in aggregate gross proceeds, before deducting underwriting discounts and commissions and offering expenses, and began trading on The Nasdaq Global Market. The IPO followed the closing of a Series C preferred stock financing of \$100 million in gross proceeds in January 2021.
- In July 2021, Gavin MacBeath, Ph.D., TScan's Chief Scientific Officer, presented findings from TScan's work to discover the targets of T cells in recovering COVID-19 patients at the Cell-Mediated Therapies for Infectious Disease Summit. The presentation also featured *in vitro* data comparing several polyepitope T cell vaccine candidates based on the Company's novel T cell target discoveries. TScan is now advancing these T cell-eliciting vaccine candidates through pre-clinical development with the goal of engineering a COVID-19 vaccine that generates long-term immunity with less susceptibility to resistance from emerging variants. In addition to addressing the current pandemic, this program represents proof-of-concept for a novel class of vaccines that are designed to elicit a long-lasting T cell response to infectious pathogens.

Upcoming Expected Milestones and Key Priorities

Liquid Tumor Programs: TScan's two lead liquid tumor TCR-T therapy candidates, TSC-100 and TSC-101, are designed to target HA-1 and HA-2, respectively, and treat patients with hematological malignancies who are undergoing allogeneic hematopoietic stem cell transplantation.

- TScan will present two posters related to TSC-100 and TSC-101 at the upcoming ASH Annual Meeting and Exposition.
 - IND-enabling studies and the submission of IND applications to the U.S. Food and Drug Administration (FDA) are planned for TSC-100 and TSC-101 during the fourth quarter 2021.
 - Following the IND submissions and pending acceptance by the FDA, clinical trials for TSC-100 and TSC-101 are expected to begin in the first half of 2022 with preliminary data expected in the second half of 2022.
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Solid Tumor Programs: TScan's TSC-200 series of TCR-T therapy candidates include a combination of known targets, such as HPV16 for TSC-200, PRAME for TSC-203, and MAGE-A1 for TSC-204, as well as targets that are novel antigens for TCR-T therapy, such as those for TSC-201 and TSC-202.

- TScan plans to present preclinical data of the TSC-2xx series during the first half of 2022.
- TScan plans to progress IND-enabling studies for the TSC-2xx series and submit IND applications during the second half of 2022, including for TSC-200 for HPV, during the second half of 2022. Further INDs are planned for 2023.

Infectious Disease Program

- Research is continuing into potential T cell-focused COVID-19 vaccine constructs utilizing TScan's novel T cell target discoveries.

Third Quarter 2021 Financial Results

As of September 30, 2021, the Company had cash and cash equivalents totaling \$182.3 million, excluding restricted cash of \$0.6 million. Based on the Company's current operating plan, TScan expects that cash and cash equivalents as of September 30, 2021, will enable it to fund its operating expenses into 2024.

Research and development expenses for the third quarter 2021 were \$14.2 million, compared to \$5.8 million for the third quarter 2020.

General and administrative expenses for the third quarter 2021 were \$4.0 million, compared to \$1.6 million for the third quarter 2020.

Net loss for the third quarter 2021 was \$15.8 million or \$0.80 per common share, compared to a net loss of \$7.2 million or \$7.16 per common share for the third quarter 2020. Net loss per share was calculated using 19.9 million weighted average common shares and 1.0 million weighted average common shares outstanding for the third quarter of 2021 and 2020, respectively.

On July 20, 2021, the Company issued 6,666,667 shares of common stock in its IPO, raising gross proceeds of \$100 million. In addition, upon closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into 15,616,272 shares of common stock (of which 5,143,134 shares are non-voting common stock). This brings the total shares outstanding as of November 5, 2021, to 23,768,036, which consists of 18,624,902 shares of voting common stock and 5,143,134 shares of non-voting common stock.

TScan's latest presentation is available on the "Events and Presentations" section of the Company's website, and can be accessed [here](#).

About TScan

TScan is a biopharmaceutical company focused on the development of T cell receptor (TCR) engineered T cell (TCR-T) therapies for the treatment of patients with cancer. The Company's lead liquid tumor TCR-T therapy candidates, TSC-100 and TSC-101, are in development for the treatment of patients with hematologic malignancies to eliminate residual leukemia and prevent relapse after hematopoietic stem

cell transplantation. The Company is also developing multiplexed TCR-T therapy candidates for the treatment of various 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, statements regarding possible or assumed future results of operations of TScan Therapeutics, Inc., expenses and financing needs, business strategies and plans, research and development plans or expectations, the structure, timing and success of the Company's planned preclinical development and clinical trials, expected milestones, market sizing, competitive position, regulatory matters, industry environment and potential growth opportunities, among other things. 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. Important factors that could cause actual results to differ materially from those reflected in TScan's forward-looking statements include, among others, 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 Final Prospectus for its initial public offering and TScan's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at <https://www.sec.gov/>. Additional factors may be described in those sections of TScan's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, expected to be filed with the SEC in the fourth quarter of 2021.

In addition to the risks described above and in TScan's other filings with the SEC, other unknown or unpredictable factors also could affect TScan's results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and TScan undertakes no obligation to update any forward-looking

statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Assets		
Cash and cash equivalents	\$ 182,312	\$ 34,791
Other assets	22,577	14,947
Total assets	<u>\$ 204,889</u>	<u>\$ 49,738</u>
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Total liabilities	\$ 30,815	\$ 32,519
Convertible preferred stock	-	59,681
Total stockholders' deficit	174,074	(42,462)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 204,889</u>	<u>\$ 49,738</u>
Common stock outstanding as of November 5, 2021	23,768,036	

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Revenue				
Collaboration and license revenue	\$ 2,412	\$ 290	\$ 7,287	\$ 290
Operating expenses:				
Research and development	14,206	5,813	32,346	\$ 14,613
General and administrative	4,048	1,648	9,380	\$ 4,100
Total operating expenses	<u>18,254</u>	<u>7,461</u>	<u>41,726</u>	<u>18,713</u>
Loss from operations	(15,842)	(7,171)	(34,439)	(18,423)
Other income	3	1	14	103
Net loss	<u>\$ (15,839)</u>	<u>\$ (7,170)</u>	<u>\$ (34,425)</u>	<u>\$ (18,320)</u>
Net loss per share, basic and diluted	<u>\$ (0.80)</u>	<u>\$ (7.16)</u>	<u>\$ (4.55)</u>	<u>\$ (20.44)</u>
Weighted average common shares outstanding—basic and diluted	<u>19,875,428</u>	<u>1,001,853</u>	<u>7,562,436</u>	<u>896,100</u>

