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): March 9, 2022

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

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 240.13d-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, $0.0001 Par Value	**TCRX**	**The Nasdaq Global Market**

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 9, 2022, TScan Therapeutics, Inc. announced its financial results for the quarter and full year ended December 31, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth 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:

99.1	Press Release dated March 9, 2022.
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 9, 2022
By: /s/ David Southwell
Title: Chief Executive Officer

TScan Therapeutics Reports Full Year 2021 Financial Results and Highlights Key 2022 Priorities

Received FDA clearance of IND for TSC-100 for the treatment of hematologic malignancies

Phase 1 umbrella trial for liquid tumor program to initiate in H1 2022; preliminary data expected in H2 2022

Two INDs for TSC-200 series anticipated by year end

Strong balance sheet with cash and cash equivalents of $161.4 million as of December 31, 2021; funds Company into 2024

WALTHAM, Mass., Mar. 9, 2022 — 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 full year ended December 31, 2021, and outlined key 2022 priorities.

“As we had guided throughout 2021, in December we filed two INDs for our liquid tumor program. We also completed construction of our now fully functional 7,000 square-foot GMP manufacturing facility. Both of these steps are instrumental in our transformation to a clinical-stage company,” said David Southwell, President and Chief Executive Officer. “We also advanced our growing pipeline of solid tumor candidates and look forward to sharing further details around these programs in the coming months.”

Recent Corporate Highlights

- In January 2022, the Company announced that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application to evaluate TSC-100 for the treatment of patients with hematologic malignancies who are undergoing allogeneic hematopoietic cell transplantation. The target of TSC-100 is the minor histocompatibility antigen HA-1, which is a lineage-specific antigen found on blood cells. The Company has now submitted the clinical protocol to Institutional Review Boards (IRBs) for the initial study sites and expects to initiate clinical trials in the first half of 2022.
- In December 2021, the Company presented two posters related to its lead liquid tumor candidates TSC-100 and TSC-101 at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition. The posters highlighted the discovery of TSC-101, as well as the manufacturing process and clinical development plan for liquid tumor candidates TSC-100 and TSC-101.
- During the fourth quarter of 2021, the Company completed the construction of a state-of-the-art good manufacturing practices (GMP) facility to manufacture Phase I/II TCR-T therapies. This facility will support the manufacturing of TSC-100 and TSC-101, as well as solid tumor candidates TSC-200, TSC-201, TSC-202, TSC-203, and TSC-204, designed to treat patients with solid tumors including head and neck, cervical, melanoma and non-small cell lung cancers.

- The Company continues to strengthen its management team with the appointment of Ray Lockard as Vice President, Quality. Mr. Lockard brings over 25 years of experience in quality, validation, supply chain and manufacturing to TScan. Mr. Lockard most recently served as Executive Director, CMC QA and External Quality at Ultragenyx Pharmaceutical Inc. Prior to that, Mr. Lockard held positions of increasing responsibility for various biotechnology and life sciences companies including Biogen Inc., Alnylam Pharmaceuticals, Inc., Precision NanoSystems, Editas Medicine, Inc., and AveXis, Inc. (now Novartis Gene Therapies). Mr. Lockard holds a B.S. in Biology from Hampden-Sydney College and an M.B.A. from the University of North Carolina, Chapel Hill, Kenan-Flagler Business School.

Upcoming Expected Milestones and Key Priorities for 2022

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 hematologic malignancies who are undergoing allogeneic hematopoietic cell transplantation.

- Initiate Phase 1 umbrella trial for TSC-100 following submission of clinical protocol to IRBs for the initial study sites, with plans to enroll patients in the first half of 2022.
- As previously disclosed, the FDA placed a clinical hold on the IND for TSC-101 in January 2022. The Company has since received written communication from the FDA asking for additional assessment of the potential for off-tumor reactivity in certain tissues. TScan is working with the agency to resolve its questions as quickly as possible. The liquid tumor trial is based on an umbrella protocol, which will allow the Company to begin the TSC-100 and control arms in the near term and to open the TSC-101 arm of the ongoing trial upon clearance of the IND.
- Present initial clinical data from the liquid tumor program at a medical meeting in the second half of 2022.

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.

- Present initial preclinical data on the TSC-200 series at a medical meeting in the first half of 2022.
- Progress IND-enabling studies for the TSC-200 series and submit two IND applications during the second half of 2022. These are expected to include TSC-200 for HPV and TSC-204 for MAGE-A1.
- In 2023, the Company plans to release initial clinical data for the TSC-200 series TCRs, as well as file further INDs for additional programs in this series.

Infectious Disease Program

- Research is continuing into potential T cell focused COVID-19 vaccine constructs utilizing TScan's novel T cell target discoveries. The Company is currently conducting preclinical studies for this program.

Full Year 2021 Financial Results

As of December 31, 2021, TScan Therapeutics had cash and cash equivalents of $161.4 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 2024.

Revenue for the year ended December 31, 2021, was $10.1 million, compared to $1.1 million for the year ended December 31, 2020 (2020 Period). This increase is due to a full year of research activities related to TScan's collaboration agreement with Novartis Institutes for Biomedical Research, on which work began in September 2020.

Research and development expenses for the year ended December 31, 2021, were $45.0 million, compared to $20.6 million for the 2020 Period. The increase of $24.4 million was primarily a result of increased personnel expenses and facility-related expenses, as well as expenses related to the progress of the Company's liquid and solid tumor programs to IND filing.

General and administrative expenses for the year ended December 31, 2021, were $13.8 million, compared to $6.7 million for the 2020 Period. The increase of $7.1 million in general and administrative expenses was primarily a result of increased personnel expenses and other miscellaneous expenses, including expenses related to the IPO and status as a public company.

For the year ended December 31, 2021, TScan Therapeutics reported a net loss of $48.6 million, compared to a net loss of $26.1 million for the 2020 Period.

As of December 31, 2021, the company had issued and outstanding shares of 24,024,467 and 23,907,597, respectively.

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 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. The Company has developed and continues to build its ImmunoBank, one of the most extensive collections of known and novel solid tumor targets across different HLA types in the TCR field.

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 possible or assumed future results of TScan's operations, 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 Annual Report on Form 10-K for the year ended December 31, 2021, expected to be filed with the SEC on or about March 9, 2022.

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

	December 31, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 161,405	$ 34,791
Other assets	26,702	14,947
Total assets	$ 188,107	$ 49,738
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Total liabilities	$ 27,329	$ 32,519
Convertible preferred stock	—	59,681
Total stockholders' equity (deficit)	160,778	(42,462)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 188,107	$ 49,738
Common stock outstanding as of December 31, 2021	23,907,597	

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

	Year Ended December 31, 2021	2020
Revenue		
Collaboration and license revenue	$ 10,141	$ 1,085
Operating expenses:		
Research and development	44,954	20,577
General and administrative	13,828	6,741
Total operating expenses	58,782	27,318
Loss from operations	(48,641)	(26,233)
Other income	16	106
Net loss	$ (48,625)	$ (26,127)
Net loss per share, basic and diluted	$ (4.17)	$ (28.52)
Weighted average common shares outstanding—basic and diluted	11,662,672	916,014