

**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): April 3, 2024

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

Delaware
(State or other jurisdiction
of incorporation)

001-40363
(Commission
File Number)

81-1065054
(I.R.S. Employer
Identification No.)

TransCode Therapeutics, Inc.
6 Liberty Square, #2382
Boston, Massachusetts 02109
(Address of principal executive offices, including zip code)

(857) 837-3099
(Registrant's telephone number, including area code)

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
Common Stock, par value \$0.0001 per share	RNAZ	The Nasdaq Capital 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 April 3, 2024, TransCode Therapeutics, Inc. issued a press release announcing its financial results and other business highlights for the fourth quarter and full year ended December 31, 2023. The full text of the press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The information under this Item 2.02 is intended to be furnished and 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

Exhibit Description

[99.1](#) [Press release of TransCode Therapeutics, Inc. \(concerning financial results\) dated April 3, 2024, furnished hereto.](#)

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.

TransCode Therapeutics, Inc.

Date: April 5, 2024

By: /s/ Thomas A. Fitzgerald

Thomas A. Fitzgerald

Interim Chief Executive Officer; Chief Financial Officer

TransCode Therapeutics Reports 2023 Results; Provides Business Update

BOSTON, April 3, 2024 - TransCode Therapeutics, Inc. (NASDAQ: RNAZ), the RNA oncology company committed to more effectively treating cancer using RNA therapeutics, today reported financial results for 2023 and recent business progress.

“We believe 2023 was extremely productive and pivotal for TransCode. We are proud to have advanced our lead therapeutic candidate, TTX-MC138, into the clinic as a first-in-class drug candidate against metastatic cancer. The year was highlighted by preliminary clinical results from our Phase 0 clinical trial with radiolabeled TTX-MC138,” said Tom Fitzgerald, interim CEO and CFO of TransCode. “Further, despite very challenging financial markets, we raised over \$25 million in equity financings, streamlined our operations for higher efficiency, and signed two strategic collaborations aimed at demonstrating the value of our TTX platform in additional applications. We also continued to achieve other important milestones, with the ultimate objective of fulfilling the promise of RNA therapeutics for oncology applications. We now look forward to our Phase 1 clinical trial of TTX-MC138 which, subject to FDA authorization, is planned to begin in mid-2024.”

Key Highlights (2023 and Q1 2024)

- IRB approval for FDA-cleared first-in-human Phase 0 clinical trial with TTX-MC138.
- First patient dosed and preliminary clinical results with radiolabeled TTX-MC138 in the Phase 0 clinical trial.
- Signed a co-research agreement with Debiopharm to develop nucleic acid therapeutics for cancer treatment.
- Signed a joint research and development agreement with Akribion Genomics to develop a CRISPR-derived technology platform for cancer treatment.
- Raised over \$25 million in equity financings in an extremely challenging financial environment.
- Refocused our development strategy, prioritizing advancing TTX-MC138 into a Phase 1 clinical trial and reducing cash burn.
- Appointed CFO Tom Fitzgerald as interim CEO and director Philippe Calais as Executive Chairman following the resignation of Michael Dudley as CEO.
- Appointed Daniel Vlock, M.D., as Chief Medical Officer (part-time).
- Regained compliance with Nasdaq’s stockholders’ equity requirement.
- Presented TransCode technology at leading cancer conferences including San Antonio Breast Cancer Symposium, AACR, OTS, and TIDES Europe.

TTX-MC138

- Reported preliminary clinical results suggesting delivery of TTX-MC138 to metastatic lesions in a patient with breast cancer metastatic to lungs, bone, and liver.
- Reported positive preclinical results in a model of glioblastoma showing successful delivery and pharmacodynamic activity in brain tumors.
- Reported positive preclinical results in a model of metastatic pancreatic adenocarcinoma showing 50% inhibition of metastatic progression compared to standard-of-care chemotherapy.
- Received second Orphan Drug Designation from FDA, for TTX-MC138 in pancreatic cancer.

TTX-siPDL1

- Reported positive preclinical results in pancreatic cancer, showing extended survival relative to standard-of-care chemotherapy.

TTX-RIGA

- Reported successful completion of animal studies in a model of melanoma showing arrest of secondary tumor progression.
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2024 Corporate and R&D Objectives

With what we expect will be a very exciting year ahead, our 2024 corporate goals, none of which are assured, are to strengthen our organization while raising sufficient capital to continue to advance our research. We will also seek to expand collaborations with strategic partners to further enhance the value of our pipeline.

2024 will also be a critical year for the clinical development of TTX-MC138 and our preclinical portfolio, as we seek to:

- Initiate a Phase 1 clinical trial with TTX-MC138 in patients with advanced solid tumors as soon as we obtain FDA authorization and relevant institutional review board approvals from investigational sites.
- Report preliminary results from the planned Phase 1 trial later this year.
- Publish preclinical results in the second half of the year supporting TTX-MC138 in glioblastoma and pancreatic cancer, TTX-siPDL1 in pancreatic cancer, and TTX-RIGA in melanoma.
- Continue preclinical studies for therapeutic candidates TTX-mRNA and TTX-CRISPR.
- Advance existing strategic partnerships and sign others around TransCode's TTX delivery platform, TTX-CRISPR, TTX-siRNA, TTX-MC138, and TTX-mRNA candidates.
- Further develop an exploratory test for miRNA-10b.
- If capital resources permit, initiate CMC development to support future IND-enabling studies with TTX-siPDL1 or TTX-RIGA candidates.

2023 Financial Highlights (amounts are approximate)

- Cash was \$2.8 million on December 31, 2023, compared to \$4.97 million on December 31, 2022.
- Research and development expenses were \$12.3 million in 2023 compared to \$10.2 million in 2022.
- General and administrative expenses were \$7.2 million in 2023 compared to \$8.4 million in 2022.
- Operating loss was \$19.4 million in 2023 compared to \$18.6 million in 2022.

Financial Guidance

TransCode expects that its cash of approximately \$2.8 million as of December 31, 2023, together with approximately \$6.2 million in net proceeds received from the sale of common stock and warrants in a January 2024 registered direct offering, will be sufficient to fund planned operations into late third quarter or early fourth quarter of 2024.

About TransCode Therapeutics

TransCode is a clinical-stage oncology company focused on treating metastatic disease. The company is committed to defeating cancer through the intelligent design and effective delivery of RNA therapeutics based on its proprietary TTX nanoparticle platform. The company's lead therapeutic candidate, TTX-MC138, is focused on treating metastatic tumors which overexpress microRNA-10b, a unique, well-documented biomarker of metastasis. In addition, TransCode is developing a portfolio of first-in-class RNA therapeutic candidates designed to overcome the challenges of RNA delivery and thus unlock therapeutic access to a variety of novel genetic targets that could be relevant to treating a variety of cancers.

Forward-Looking Statements

This release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements about the occurrence or expected timing and outcome of the Phase 1 clinical trial, statements concerning the conduct and results of clinical trials, statements concerning the occurrence or the timing and outcome of expected regulatory filings, statements concerning the effects of any of our therapeutic candidates, statements concerning preclinical studies and the outcomes of those studies, statements about what trials may indicate about the effects of any of our therapeutic candidates, statements concerning our research programs, statements about TransCode’s goals to advance its therapeutic candidate portfolio, statements concerning collaborations with other parties, statements concerning TransCode’s development programs and its TTX technology platform generally and statements concerning TransCode’s financial position and cash runway. Any forward-looking statements in this press release are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the risk associated with drug discovery and development; the risk that the results of our clinical trials will not be consistent with our pre-clinical studies or expectations or with preceding clinical trials; risks associated with the timing and outcome of TransCode’s planned regulatory submissions; risks associated with TransCode’s conduct of clinical trials; risks associated with obtaining, maintaining and protecting intellectual property; risks associated with TransCode’s ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; risks of competition from other companies developing products for similar uses; risks associated with TransCode’s financial condition and its need to obtain additional funding to support its business activities, including TransCode’s ability to continue as a going concern; risks associated with TransCode’s dependence on third parties; and risks associated with geopolitical events and pandemics, including the COVID-19 coronavirus. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause TransCode’s actual results to differ from those contained in or implied by the forward-looking statements, see the section entitled “Risk Factors” in TransCode’s Annual Report on Form 10-K for the year ended December 31, 2023, as well as discussions of potential risks, uncertainties and other important factors in any subsequent TransCode filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release; TransCode undertakes no duty to update this information unless required by law.

For more information, please contact:

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