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 31, 2023

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

Delaware	**001-40363**	**81-1065054**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 March 31, 2023, TransCode Therapeutics, Inc. issued a press release announcing its financial results for the year ended December 31, 2022. 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 March 31, 2023, 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: March 31, 2023

By: /s/ Thomas A. Fitzgerald
Thomas A. Fitzgerald
Chief Financial Officer

Exhibit 99.1

TransCode Therapeutics Reports 2022 Results; Provides Business Update

BOSTON – March 31, 2023 – TransCode Therapeutics, Inc. (NASDAQ: RNAZ), the RNA oncology company committed to defeating cancer using RNA therapeutics, today reported financial results for 2022 and recent business progress.

“Despite the continued turbulence in the biotech sector, 2022 was extremely productive and, we believe, successful for TransCode. The year was highlighted by FDA’s approval to proceed with our planned Phase 0, First-In-Human, clinical trial with our lead therapeutic candidate in cancer patients with advanced solid tumors,” said Michael Dudley, Co-Founder, President and CEO of TransCode. “We achieved many important milestones, advancing our pipeline of therapeutic candidates enabled by our proprietary delivery platform. We also continued to de-risk our therapeutic candidates as we march toward the clinic to treat cancer patients using a variety of RNA approaches.”

TransCode’s Co-Founder and Chief Technology Officer, Dr. Zdravka Medarova, added, “We made a great deal of progress advancing all of our therapeutic candidates in 2022 and are excited to continue that progress with TTX-CRISPR, TTX-mRNA and TTX-RIGA . We are looking forward to the upcoming FIH clinical trial that we hope will advance our potential to deliver RNA therapeutics to tumors and metastases in cancer patients”.

Key 2022 Highlights

- Received written FDA authorization to conduct our Phase 0, First-In-Human, clinical trial with TTX-MC138, our lead therapeutic candidate
- Announced strategic alliance with The University of Texas MD Anderson Cancer Center
- Received Orphan Drug Designation (ODD) for TTX-siPDL1 in pancreatic cancer
- Achieved positive preclinical results in pancreatic cancer with both TTX-MC138 and TTX-SiPLDL1
- Expanded our RNA oncology patent portfolio
- Appointed Dr. Frank Slack (Director of the HMS Initiative for RNA Medicine) to our scientific advisory board

Recent Milestone Achievements

Therapeutic Candidates

- TTX-MC138
  - Significant progress toward completion of IND-enabling studies to support filing an IND application for a Phase I/2 clinical trial with TTX-MC138
  - Positive preclinical results with TTX-MC138 in pancreatic adenocarcinoma; 40% of animals treated with TTX-MC138 had complete responses, defined as complete regression of disease and long-term survival without recurrence
  - Received second ODD from FDA, for TTX-MC138 in pancreatic cancer

- TTX-siPDL1
    - Positive preclinical results in pancreatic cancer. In contrast to traditional monoclonal antibody checkpoint inhibitors, TTX-siPDL1 is designed to inhibit PD-L1 expression on tumor cells post-transcriptionally via the RNA interference mechanism. We believe this approach is advantageous over small molecules or antibodies because use of siRNA to inhibit the target antigen at the post-transcriptional level rather than at the protein level, means that the antigen is never synthesized by the cell

- TTX-RIGA
    - Reported successful proof-of-mechanism studies using our immunotherapy candidate and began preclinical animal studies in melanoma

Facilities

- Moved into new lab and office facilities in Newton, MA

Expected Upcoming Milestones

TransCode's goals to continue to advance its portfolio include:

- TTX-MC138
    - Obtain institutional review board approval of our FIH Phase 0 clinical study at the center where we plan to conduct the trial in up to 12 cancer patients with advanced solid tumors
    - Report topline data readout from the Phase 0 trial
    - Publish preclinical results supporting TTX-MC138 in pancreatic cancer and TTX-RIGA in melanoma
- Continue preclinical *in vivo* studies for therapeutic candidates TTX-mRNA, TTX-RIGA, TTX-CRISPR
- We are continuing to develop a broad patent portfolio meant to protect our intellectual property. Our intellectual property, which includes proprietary know-how as well as various patents, applies not only to our licensed compounds but also to other technologies owned by or licensed to TransCode
- Publish preclinical results supporting TTX-MC138 in glioblastoma
- Complete IND-enabling studies to support filing an IND application for a Phase I/2 clinical trial of TTX-MC138

2022 Financial Highlights (approximate amounts)

- Cash was $5.0 million at December 31, 2022, compared to $20.8 million at December 31, 2021
- Research and development expenses were $10.5 million in 2022 compared to $2.8 million in 2021*
- General and administrative expenses were $8.5 million in 2022 compared to $3.4 million in 2021*
- Operating loss was $17.9 million in 2022 compared to $6.8 million in 2021*

*Not fully comparable as meaningful operations only commenced in July 2021, after our IPO

Financial Guidance

TransCode expects that its cash of approximately $5.0 million as of December 31, 2022, together with approximately $1.3M in net proceeds received from the sale of common stock in its February 2023 registered direct offering and $871 thousand of additional funding expected in the second quarter of 2023 for the third year of its SBIR award will be sufficient to fund planned operations into but not through the second quarter of 2023.

About TransCode Therapeutics

TransCode is an RNA oncology company created on the belief that cancer can be more effectively treated using RNA therapeutics. The Company has created a platform of drug candidates designed to target a variety of tumor types with the objective of significantly improving patient outcomes. The Company's lead therapeutic candidate, TTX-MC138, is focused on treating metastatic cancer, which is believed to cause approximately 90% of all cancer deaths totaling over nine million per year worldwide. The Company believes that TTX-MC138 has the potential to dramatically improve clinical outcomes in a range of cancers, including breast, pancreatic, ovarian and colon cancer, glioblastomas and others. Two of the Company's other drug candidates, TTX-siPDL1 and TTX-siLIN28B, focus on treating tumors by targeting PD-L1 and LIN28B, respectively. TransCode also has two indication-agnostic programs: TTX-RIGA, an RNA–based agonist of the retinoic acid-inducible gene I designed to activate an innate immune response in cancer; and TTX-CRISPR, a CRISPR/Cas9–based therapeutic platform for the repair or elimination of cancer-causing genes. TransCode is also developing TTX-mRNA, an mRNA-based platform for the development of cancer vaccines designed to activate cytotoxic immune responses against tumor cells.

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 concerning the potential clinical benefits of TTX-MC138, statements concerning the occurrence or expected timing and outcome of the Phase 0 clinical trial, including whether this trial will demonstrate proof-of-mechanism, statements concerning Orphan Drug Designation, statements concerning the occurrence or the timing and outcome of expected regulatory filings, statements concerning the effects any of our therapeutic candidates , statements concerning preclinical studies and the outcomes of those studies, statements about what early trials may indicate about the effects of any of our therapeutic candidates, statements concerning our research programs, our new delivery platform, and intellectual property, statements concerning our IND-enabling studies, statements about TransCode's goals to advance its therapeutic candidate portfolio, statements concerning collaborations with other parties, and statements concerning TransCode's development programs and its TTX technology platform generally. Of note, a Phase 0 clinical trial is an exploratory study, conducted under an exploratory Investigational New Drug (eIND) application. Exploratory IND studies usually involve very limited human exposure to a therapeutic candidate to evaluate mechanism of action in order to inform potential clinical evaluation in future clinical studies, but otherwise have no therapeutic intent. 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 planned clinical trials will not be consistent with our preclinical studies or expectations; risks associated with the timing and outcome of TransCode's planned regulatory submissions; risks associated with TransCode's planned clinical trials for its therapeutic candidates; 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; the risk 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; the risk that TransCode's common stock could be delisted from the Nasdaq Capital Market if it is unable to regain compliance with the minimum bid price requirement; and risks associated with 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 period ended December 31, 2022, 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:

TransCode Therapeutics, Inc.
Alan Freidman, VP Investor Relations
alan.freidman@transcodetherapeutics.com