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): October 24, 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 or to be 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 8.01 Other Events.

On October 24, 2023, Transcode Therapeutics, Inc. announced preliminary clinical results in first patient enrolled in Phase 0 clinical study. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release of TransCode Therapeutics, Inc. dated October 24, 2023.
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: October 24, 2023

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

Exhibit 99.1

TRANSCODE

THERAPEUTICS™

TransCode Therapeutics Announces Preliminary Clinical Results in First Patient in Phase 0 Clinical Study with Lead Therapeutic Candidate, TTX-MC138

Evidence of Drug Accumulation in Metastatic Lesions

BOSTON October 24, 2023 – TransCode Therapeutics, Inc. (NASDAQ: RNAZ), the RNA oncology company committed to more effectively treating cancer using RNA therapeutics, today announced preliminary results with its lead therapeutic candidate, TTX-MC138, in the first patient enrolled in its Phase 0 clinical trial aimed at demonstrating delivery of TTX-MC138 to metastatic cancer, including metastases beyond those found in the liver. These preliminary data showed that radioactivity consistent with accumulation of TTX-MC138 was detected by noninvasive imaging in the regions of the metastatic lesions previously identified by fluorodeoxyglucose (FDG)/positron emission tomography (PET) (FDG/PET). In addition, radiolabeled TTX-MC138 had pharmacokinetic behavior consistent with that expected based on non-clinical IND-enabling studies. The patient tolerated the dosing with no reported adverse reactions. Metabolite analysis indicated circulation of intact radiolabeled TTX-MC138 for more than 20 hours, equivalent to that predicted by Drug Metabolism and Pharmacokinetics (DMPK) modelling, and that the drug candidate analyzed in the blood was identical to that of the manufactured drug candidate, demonstrating *in vivo* stability. Complete analysis of data from this first patient is in process and will be included in the final report for all patients enrolled in the study.

TransCode's Chief Technology Officer, Zdravka Medarova, PhD, commented, "We believe these preliminary clinical data support our thesis that TTX-MC138 can be delivered successfully to metastatic lesions for the potential treatment of metastatic cancer. Preclinical evidence pointing towards miRNA-10b's critical role in metastatic progression across a number of major cancer types suggests that inhibition of miRNA-10b in patients with advanced disease could have a dramatic impact on their disease."

The Phase 0 trial is an open-label, single-center, microdose study intended to demonstrate delivery of the radiolabeled version of TTX-MC138 to radiographically-confirmed metastases in subjects with advanced solid tumors. Up to 12 subjects may be enrolled in this clinical study, each of which is expected to receive a single microdose of radiolabeled TTX-MC138 followed by positron emission tomography/magnetic resonance imaging (PET-MRI) and blood analyses. The trial is intended to quantify the amount of TTX-MC138 delivered to metastatic lesions, especially beyond the liver, and the pharmacokinetics of the therapeutic candidate in those patients. The trial is intended to yield important data regarding TTX-MC138 delivery to clinical metastases that could inform dose selection and frequency, for further clinical development. The trial is not intended to demonstrate a therapeutic effect.

In the earlier IND-enabling studies conducted in non-human primates (NHP), TTX-MC138 demonstrated long circulation and tissue distribution consistent with hepatic clearance. Data from the NHP study were incorporated into a DMPK model, intended to model the pharmacokinetics and tissue distribution of TTX-MC138 in humans. The model predicted circulation and tissue distribution in humans consistent with results from TransCode's nonclinical studies in which numerous complete regressions of metastatic disease were observed.

TTX-MC138 consists of an iron oxide nanocarrier conjugated to a nucleic acid specifically designed to inhibit the oncogenic RNA, microRNA-10b. MiRNA-10b has been described as the master regulator of cancer progression in a number of advanced solid tumors. TransCode believes that TTX-MC138 has the potential to become a treatment for many of these cancers. Administration of TTX-MC138 has demonstrated complete regression of metastatic disease in a number of mouse models of pancreatic and breast cancer. In addition, TTX-MC138 was successfully delivered and demonstrated bioactivity in a case study of spontaneous feline mammary carcinoma.

“Our Phase 0 trial involves a single microdose of radiolabeled TTX-MC138 followed by noninvasive PET-MRI imaging and metabolite analysis. Given the similarities between humans and non-human primates relative to anatomy, physiology, and molecular biology, we anticipated results in trial patients comparable to those observed in the DMPK model based on our NHP studies, as evidenced by the preliminary data we announced today,” added Michael Dudley, Chief Executive Officer of TransCode.

This study was done in collaboration with Andreas Varkaris, MD, PhD, an attending physician and investigator for the Termeer Center for Targeted Therapies at Massachusetts General Hospital and the principal investigator of TransCode’s study.

About TransCode Therapeutics

TransCode is an RNA oncology company created on the belief that cancer can be more effectively treated using RNA therapeutics. Using its iron oxide nanoparticle delivery platform, the Company has created a portfolio 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. Another of the Company’s drug candidates, TTX-siPDL1, focuses on treating tumors by targeting a protein called Programmed death-ligand 1 (PD-L1). TransCode also has three cancer-agnostic programs: TTX-RIGA, an RNA–based agonist of the retinoic acid-inducible gene I designed to drive an immune response in the tumor microenvironment; TTX-CRISPR, a CRISPR/Cas9–based therapy platform for the repair or elimination of cancer-causing genes inside tumor cells; and 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 preliminary first patient results of the Phase 0 clinical trial of radiolabeled TTX-MC138, statements concerning expected clinical results of TransCode’s therapeutic candidates, statements concerning the results of RNA research, statements concerning the potential for treating cancer with RNA therapeutics, statements concerning the timing and outcome of expected regulatory filings and clinical trials, including the current first-in-human study of TTX-MC138, and whether this study will demonstrate proof-of-mechanism, and statements concerning TransCode’s portfolio of drug candidates and 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. Further, caution should be taken when interpreting the preliminary results of the Phase 0 trial. This data may differ from future results of this study, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. 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 clinical trials we conduct will not be consistent with our pre-clinical 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 product 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; 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 year 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:

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