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 30, 2022

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 7.01 Regulation FD Disclosure.

On November 30, 2022, TransCode Therapeutics, Inc. (the "Company") issued a press release announcing its submission of an exploratory Investigational New Drug ("eIND") application to the U.S. Food and Drug Administration ("FDA") for a planned First-in-Human Phase 0 clinical trial for the Company's lead therapeutic candidate, TTX-MC138. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they 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 8.01 Other Events.

On November 30, 2022, the Company announced its submission of an exploratory Investigational New Drug ("eIND") application to the U.S. Food and Drug Administration ("FDA") for a planned First-in-Human Phase 0 clinical trial for the Company's lead therapeutic candidate, TTX-MC138.

The planned trial is intended to quantify the amount of radiolabeled TTX-MC138 delivered to metastatic lesions and the pharmacokinetics and biodistribution of the therapeutic candidate in cancer patients. The trial could yield critical data regarding therapeutic dose, timing, and potential safety and could inform later stage clinical trials. This trial is not intended to demonstrate any therapeutic effect.

The FDA is expected to review this application and determine the acceptability of the data before TransCode can begin dosing patients. As with FDA review of Investigational New Drug applications submitted for Phase 1 clinical trials, an eIND becomes effective 30 days after receipt by the FDA unless FDA, within the 30-day time period, raises concerns or questions about the content of the eIND or clinical trial design.

Forward-Looking Statements

This Form 8-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements concerning the occurrence or the timing and outcome of expected regulatory filings, including the FDA's review of the eIND application, statements concerning the occurrence or expected timing and outcome of this trial, including whether this trial will demonstrate proof-of-mechanism, statements concerning the effects any of our treatments may deliver in the future and whether they will successfully deliver certain outcomes where other treatments have failed, statements concerning preclinical studies and the outcomes of those studies, statements about what early trials may indicate about the effects of any of our drug candidates, statements about TransCode's goals to advance its drug portfolio, statements concerning our financial condition, financial results, and financial expectations, 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 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 Form 8-K 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 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 period ended December 31, 2021, 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 Form 8-K is as of the date of the filing of the Form 8-K; TransCode undertakes no duty to update this information unless required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release of TransCode Therapeutics, Inc. dated November 30, 2022.
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: November 30, 2022

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

Exhibit 99.1

TransCode Therapeutics Announces eIND Submission to US FDA for Planned First-in-Human Clinical Trial in Patients with Advanced Solid Tumors

BOSTON – November 30, 2022 – TransCode Therapeutics, Inc. (NASDAQ: RNAZ), the RNA oncology company committed to more effectively treating cancer using RNA therapeutics, announced today that it has submitted an exploratory Investigational New Drug (eIND) application to the U.S. Food and Drug Administration (FDA) for a planned First-in-Human Phase 0 clinical trial. The planned clinical trial is to evaluate TransCode's lead therapeutic candidate, TTX-MC138, in cancer patients with advanced solid tumors. TTX-MC138 is designed to inhibit the pro-metastatic RNA, microRNA-10b, described as the master regulator of metastasis in a number of advanced solid tumors. TransCode believes that TTX-MC138 could be used as a treatment for many of these cancers.

"We are very excited to take this next step in the development of TTX-MC138 which we hope will bring us closer to introducing this first of its kind treatment for metastatic disease," said TransCode's Chief Executive Officer and co-founder, Michael Dudley. "We are hopeful that the study conducted under the eIND will demonstrate successful delivery of our lead therapeutic candidate to metastatic lesions in patients with advanced solid tumors. The delivery of oligonucleotide therapeutics to sites other than the liver has remained a significant challenge for decades. Overcoming this challenge would represent an unprecedented step in unlocking therapeutic access to a variety of well documented genetic targets involved in a range of cancers and beyond."

The company believes that TTX-MC138 has the potential to produce regression without recurrence in a range of cancers, including breast, pancreatic, ovarian and colon cancer, glioblastomas and others. In multiple preclinical murine models of triple-negative breast cancer (TNBC), treatment with low-dose chemotherapy and TTX-MC138 eliminated pre-existing local metastases in 100% of treated animals representative of stage II/III metastatic cancer. In a more aggressive model representative of stage IV metastatic cancer, treatment with low-dose chemotherapy and TTX-MC138 resulted in elimination of distant metastases in 65% of animals treated. In a murine model of pancreatic adenocarcinoma, TTX-MC138, administered as monotherapy, resulted in complete responses, manifested as regression without recurrence, in 40% of treated animals. In addition to murine models of cancer, TTX-MC138 was successfully delivered and demonstrated preliminary efficacy in a case study of spontaneous feline mammary carcinoma.

TransCode's Chief Technology Officer and co-founder, Dr. Zdravka Medarova, said, "Demonstrating the feasibility of delivering TTX-MC138 to malignant lesions in humans could unlock the potential of a wide array of RNA-targeted therapeutics, since the TTX platform permits a modular drug design, centered around the same delivery vehicle but with different payloads in terms of the sequence, design, and mechanism of action of the nucleic acid that is being delivered."

A Phase 0 clinical trial is an exploratory study conducted under an Investigational New Drug application. Exploratory IND studies usually involve very limited human exposure to a therapeutic candidate; their primary purpose is to evaluate the candidate's safety and mechanism of action. In TransCode's planned clinical trial, up to 12 patients will be given a single dose of radiolabeled TTX-MC138 followed by noninvasive positron emission tomography-magnetic resonance imaging (PET-MRI). The trial is intended to quantify the amount of radiolabeled TTX-MC138 delivered to metastatic lesions and the pharmacokinetics and biodistribution of the therapeutic candidate in cancer patients. The trial could yield critical data regarding therapeutic dose, timing, and potential safety and could inform later stage clinical trials. This trial is not intended to demonstrate any therapeutic effect.

The eIND application includes data, reports and overview summaries of numerous studies that characterize the pharmacology, pharmacokinetics, and toxicology of the clinical trial version of TTX-MC138 both *in vitro* and *in vivo*. Additionally, the application describes the chemistry, manufacturing and control (CMC) production of the drug substance and drug product to be used in the trial. The main purpose of the eIND application is to provide FDA with extensive nonclinical data supporting an acceptable safety profile of a therapeutic candidate to be administered to humans. The FDA is expected to review this application and determine the acceptability of the data before TransCode can begin dosing patients. As with FDA review of Investigational New Drug (IND) applications submitted for Phase 1 clinical trials, an eIND becomes effective 30 days after receipt by the FDA unless FDA, within the 30-day time period, raises concerns or questions about the content of the eIND or clinical trial design.

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 produce regression without recurrence 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 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.

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For more information, please contact:

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