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 15, 2021

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, $0.0001 par value 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 November 15, 2021, TransCode Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2021. 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

99.1	Press release of TransCode Therapeutics, Inc. (concerning financial results) dated November 15, 2021, 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: November 15, 2021

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

Exhibit 99.1

TransCode Therapeutics Reports Business Progress and Third Quarter 2021 Financial Results

eIND application submission for TTX-MC138 anticipated in H1 2022

Boston, MA, Nov 15, 2021 – TransCode Therapeutics, Inc. (Nasdaq: RNAZ), an RNA oncology company created on the belief that cancer can be defeated through the intelligent design and effective delivery of RNA therapeutics, today reported recent business progress and third quarter 2021 financial results.

"TransCode has made further progress across our corporate infrastructure and bourgeoning portfolio, advancing our mission to design RNA therapeutics that can effectively treat cancer. Reflecting the results of an important microdosing study recently reported in *Cancer Nanotechnology*, TransCode believes it has an opportunity in its planned First-in-Human (FIH) Phase 0 clinical trial of its lead therapeutic candidate, TTM-MC138, to obtain results that will better inform designs of planned follow-on trials than the original FIH trial design. The reported study was conducted by Dr. Zdravka Medarova, a scientific co-founder of TransCode Therapeutics who was appointed Chief Technology Officer effective October 1." said Michael Dudley, co-founder, president and CEO of TransCode Therapeutics. Dr. Medarova noted, "We believe a microdosing study offers the potential to more definitively establish proof-of-mechanism for our delivery platform, upon which we hope to build a broad and diverse pipeline of therapeutics and diagnostics with the potential to reach previously undruggable genetic targets."

Dudley added, "We are striving to file our exploratory Investigational New Drug Application (eIND) required for the FIH trial by the end of the first quarter 2022, although because of COVID-19-related backlogs at contract research organizations, the filing may be later in the first half. Regardless, we believe the proposed microdosing study should, if successful, demonstrate the power and versatility of our TTX platform in solving the challenges of RNA delivery in oncology. In addition, we have continued IND-enabling work for TTX-MC138 and remain on track to file an IND for a Phase I clinical trial for treatment of metastatic disease by year end 2022."

Third Quarter 2021 and Recent Highlights

- Expanded the Company's executive team with the appointment of TransCode's scientific co-founder, Zdravka Medarova, Ph.D., as Chief Technology Officer effective October 1. Dr. Medarova is a leader in the field of non-coding RNA delivery to cancer and has authored multiple high-impact publications on the topic of RNA delivery, nanotechnology, and the biology of cancer metastasis.

- Continued eIND-enabling activities for TTX-MC138, the Company's lead program, targeting micoRNA-10b (miR-10b) for treatment of metastatic solid tumors. Due to continued COVID-19-related backlogs at contract research organizations, the planned eIND filing may be in the second quarter 2022. Concurrently, IND-enabling efforts remain on track to support an IND expected to be filed in 2H 2022 for a planned Phase 1 study of TTX-MC138.

- Announced publication of preclinical results supporting TTX-MC138 in *Cancer Nanotechnology*, based on research conducted at the Athinoula A. Martinos Center for Biomedical Imaging in the Department of Radiology at Massachusetts General Hospital and Harvard Medical School. The key results of the study demonstrated that a radiolabeled derivative of TTX-MC138, when injected intravenously, accumulated in metastatic lesions, confirming its intended pharmacokinetic profile.

- Based on joint research conducted at Michigan State University and the Athinoula A. Martinos Center for Biomedical Imaging in the Department of Radiology and Massachusetts General Hospital and Harvard Medical School, additional preclinical data were published in *Oncotarget* highlighting the potential for microRNA-based therapies in glioblastoma multiforme (GBM). The publication included *in vivo* animal studies confirming the inhibitory effect of TTX-MC138 on the growth of stem cell-derived orthotopic GBM xenografts, suggesting miR-10b may represent a useful target in GBM therapy.

- Conversion of the Company's convertible promissory notes into common stock upon completion of the initial public offering (IPO) in July.

Key Planned Upcoming Milestones

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

- TTX-MC138
    - Submission to FDA of an eIND application by second quarter 2022.
    - Initiation of a FIH Phase 0 clinical study evaluating TTX-MC138 for treatment of metastatic solid tumors later in 2022.
    - Concurrent completion of IND-enabling studies to support a second half 2022 filing of an IND application for a Phase I clinical trial of TTX-MC138.
- Publication in the first half of 2022 of preclinical results supporting the TTX delivery platform in pancreatic cancer and glioblastoma multiforme.
- Filing of additional patents related to new and current technologies.
- Continuation of pre-clinical studies for therapeutic candidates TTX-RIGA, TTX-siPDL1 and TTX-siLin28b

Third Quarter Financial Highlights

- **Cash and Cash Equivalents:** As of September 30, 2021, cash and cash equivalents totaled approximately $22.5 million largely reflecting the net proceeds from the July IPO.
- **R&D Expenses:** Research and development expenses were approximately $993 thousand in the third quarter of 2021, compared to approximately $54 thousand in the third quarter of 2020. The increase was primarily due to purchases of materials, compensation costs which the Company did not have prior to the third quarter of 2021 except for stock-compensation expenses, license fees, intellectual property expenses, and lab facility expenses.
- **G&A Expenses:** General and administrative expenses were approximately $1.4 million in the third quarter of 2021, compared to approximately $186 thousand in the third quarter of 2020. The increase was primarily due to increased liability insurance costs, compensation and related personnel costs which the Company did not have in the 2020 period except for stock- compensation expenses, investor relations and other costs of being a public company, and expenses for legal, accounting and tax services.
- **Operating Loss:** Operating loss was approximately $2.4 million in the third quarter of 2021, compared to approximately $239 thousand in the third quarter of 2020. Net loss for the 2021 third quarter was approximately $2.3 million, or $0.20 per basic and diluted share, compared to a net loss of approximately $1.4 million, or $0.30 per basic and diluted share, for the third quarter of 2020. The Company expects that operating losses will increase substantially in the foreseeable future.

Financial Guidance

TransCode expects that its cash and cash equivalents as of September 30, 2021, together with additional funding expected from an April 2021 SBIR award, are sufficient to fund planned operations through year-end 2022.

About TransCode Therapeutics

TransCode is an emerging RNA oncology company created on the belief that cancer can be defeated through the intelligent design and effective delivery of 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 representing over nine million deaths 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 the treatment of tumors by targeting PD-L1 and Lin28b, respectively. The Company is also developing other therapeutic candidates and diagnostic products related to its planned therapeutics business.

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 timing and outcome of expected regulatory filings, including the filing of an eIND for the planned first-in-human study of TTX-MC138, and statements concerning the timing and outcome of this study, including whether this study will demonstrate proof-of-concept, statements concerning TransCode's development programs and TTX technology platform generally, and statements about TransCode's cash burn and ability to fund operations through year-end 2022. 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 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 Quarterly Report on Form 10-Q for the period ended September 30, 2021, as well as discussions of potential risks, uncertainties and other important factors in TransCode's subsequent 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.

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Balance Sheet Data
(unaudited)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 22,499,856	$ 828,016
Prepaid expenses and other current assets	2,704,386	3,199
Deferred offering costs	--	224,153
Total assets	25,359,852	1,055,368
Accounts payable and accrued expenses	1,984,657	369,177
Deferred grant income	220,075	--
Convertible promissory notes, net of debt issuance costs and debt discount	--	2,086,675
Accrued interest – convertible promissory notes	--	191,687
Derivative liabilities	--	1,751,000
Total stockholders' equity (deficit)	23,155,120	(3,408,232)

Statement of Operations Data
(unaudited)

	Three Months Ended September 30,	
	2021	2020
Operating expenses:		
Research and development	$ 992,946	$ 53,936
General and administrative	1,366,963	185,555
Total operating expenses	2,359,909	239,491
Loss from operations	(2,359,909)	(239,491)
Other income (expenses), net	30,203	(1,134,413)
Loss before income taxes	(2,329,706)	(1,373,904)
Net loss	$ (2,329,706)	$ (1,373,904)
Weighted average common shares outstanding	11,526,514	4,636,216
Basic and diluted loss per share	$ (0.20)	$ (0.30)

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