
**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): August 23, 2021

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))

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
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 August 23, 2021, TransCode Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 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 August 23, 2021, furnished hereto.](#)

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: August 23, 2021

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

TransCode Therapeutics Reports Business Progress and Second Quarter 2021 Financial Results

Completed initial public offering of common stock, raising \$28.8 million in gross proceeds

Awarded \$2.3 million in funding from NIH to support clinical evaluation of TTX-MC138

On track to submit eIND application for TTX-MC138 in Q1 2022

Boston, MA, Aug 23, 2021 – TransCode Therapeutics, Inc. (Nasdaq: RNAZ), an emerging 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 second quarter 2021 financial results.

“2021 has so far been foundational for TransCode, highlighted by our recent initial public offering and listing on Nasdaq. With resources from the IPO and additional support from the NIH, we are driving progress across our organization, including key staff additions who bring valued expertise to our team and advancement of our preclinical work,” said Michael Dudley, co-founder, president and CEO of TransCode Therapeutics. “Looking forward, we are positioning to move our pipeline into clinical development, as we seek to demonstrate the power and versatility of our TTX platform in solving the challenges of RNA delivery in oncology. We remain on track to submit an exploratory Investigational New Drug Application (eIND) in the first quarter of 2022 to test our lead therapeutic candidate, TTX-MC138, in a Phase 0 study in metastatic solid tumors. We believe this study has the potential to establish proof-of-mechanism for our 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.”

Second Quarter 2021 and Recent Highlights

- Completed an initial public offering of 7,187,500 shares of common stock, including full exercise of the underwriters’ option to purchase additional shares, resulting in aggregate gross proceeds of \$28.8 million, before deducting underwriting discounts and commissions and other offering expenses.
 - Awarded a Fast-Track Small Business Innovation Research (SBIR) grant from National Institutes of Health (NIH), totaling \$2.3 million expected over three years to support the clinical evaluation of TTX-MC138. The Company expects to use these funds for translational experiments to identify and optimize a method for measuring miR-10b expression in breast cancer clinical samples, as well as IND-enabling activities and measurement of delivery and target engagement of TTX-MC138.
 - Strengthened the Company’s leadership team with several key appointments, including:
 - o Judy Carmody, Ph.D., as SVP of Operations, Susan Duggan as VP of Clinical Operations, Dustan Bonnin as VP of Corporate Strategy and Subrata Ghosh, Ph.D., as Principal Scientist; and
 - o Dejan Juric, M.D., appointed to its Scientific Advisory Board. Dr. Juric, a renowned expert in personalized cancer medicine and breast cancer specialist, is currently serving as director of the Henri and Belinda Termmeer Center for Targeted Therapies and Investigational Cancer Therapeutics Program at Massachusetts General Hospital.
 - Advanced preclinical work for TTX-MC138, the Company’s lead program, targeting miR-10b for treatment of metastatic solid tumors. The Company has completed development of a diagnostic assay validating a method for measuring miR-10b expression in patient blood and tissue samples. This new assay should support future TTX-MC138 clinical trials including the initial Phase 0 study.
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- Initiated IND-enabling activities to support its planned eIND filing for TTX-MC138.

Planned Upcoming Milestones

TransCode continues to advance its portfolio and has set the following goals:

- TTX-MC138
 - o Submission to FDA of an eIND application in the first quarter of 2022.
 - o Initiation of Phase 0 clinical study evaluating TTX-MC138 for treatment of metastatic solid tumors later in 2022.
 - o Concurrent completion of IND-enabling studies to support second half of 2022 filing an IND application for a Phase I clinical trial of TTX-MC138.
- Publication of preclinical results supporting its TTX delivery platform in the second half of 2021.

Second Quarter Financial Highlights

- **Cash and Cash Equivalents:** As of June 30, 2021, cash and cash equivalents totaled approximately \$80 thousand, excluding approximately \$25.4 million in net proceeds from the Company's July IPO.
- **R&D Expenses:** Research and development expenses were approximately \$212 thousand in the second quarter of 2021, compared to approximately \$75 thousand in the second quarter of 2020. The increase was primarily due to purchases of materials, license fees, lab facility expenses, costs related to development of intellectual property, and share-based compensation expenses.
- **G&A Expenses:** General and administrative expenses were approximately \$144 thousand in the second quarter of 2021, compared to approximately \$177 thousand in the second quarter of 2020. The increase was primarily due to increased legal, accounting, insurance, and investor relations costs associated with the Company's IPO and to share-based compensation expenses.
- **Operating Income (Loss):** Operating loss was approximately \$356 thousand in the second quarter of 2021, compared to approximately \$92 thousand in the second quarter of 2020. Net income was approximately \$2.8 million, or \$0.60 per basic share and \$0.51 per diluted share, for the second quarter of 2021, compared to a net loss of approximately \$127 thousand, or \$0.03 per basic and diluted share, for the second quarter of 2020. The results in the second quarter of 2021 primarily reflect a change in fair value of derivative liabilities related to convertible promissory notes. The convertible promissory notes automatically converted into common stock upon completion of the IPO. In the foreseeable future, the Company expects that operating losses will increase substantially and does not expect net profits.

Financial Guidance

TransCode expects that its cash and cash equivalents as of June 30, 2021, together with net proceeds from its initial public offering and the 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 causes 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. 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 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, and statements concerning TransCode’s development programs and TTX technology platform generally. 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 June 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)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	\$ 79,567	\$ 828,016
Prepaid expenses and other current assets	460,652	3,199
Deferred offering costs	890,452	224,153
Total assets	1,522,265	1,055,368
Accounts payable and accrued expenses	1,216,501	369,177
Deferred grant income	251,810	--
Convertible promissory notes, net of debt issuance costs and debt discount	2,125,813	2,086,675
Accrued interest – convertible promissory notes	247,285	191,687
Derivative liabilities	2,618,000	1,751,000
Total stockholders' equity (deficit)	(5,036,081)	(3,408,232)

Statement of Operations Data
(unaudited)

	Three Months Ended June 30,	
	2021	2020
Operating expenses:		
Research and development	\$ 211,752	\$ 75,000
General and administrative	143,776	16,605
Total operating expenses	355,528	91,605
Loss from operations	(355,528)	(91,605)
Other income (expenses), net	3,126,432	(35,593)
Income (loss) before income taxes	2,770,904	(127,198)
Net income (loss)	\$ 2,770,904	\$ (127,198)
Basic earnings (loss) per share	\$ 0.60	\$ (0.03)
Diluted earnings (loss) per share	\$ 0.51	\$ (0.03)

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