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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 001-40363

TRANSCODE THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**81-1065054**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
6 Liberty Square, #2382 Boston, Massachusetts	**02109**
(Address of Principal Executive Offices)	**(Zip Code)**

(857) 837-3099
(Registrant's Telephone Number, Including Area Code)

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, $0.0001 par value per share	RNAZ	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

At August 4, 2023, the registrant had 2,025,674 shares of Common Stock, $0.0001 par value per share, outstanding.

TRANSCODE THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are including this statement for purposes of complying with those safe harbor provisions. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “could,” “expects,” “plans,” “intends,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our estimates and expectations regarding our capital requirements, cash and expense levels, liquidity sources and our ability to obtain, on satisfactory terms or at all, the financing required to support operations, research, development, clinical trials, and commercialization of products;
- the results and timing of our preclinical and clinical trial activities;
- a potential delisting of our common stock from trading on the Nasdaq Capital Market if our stockholders’ equity does not meet and maintain the $2.5 million minimum Nasdaq threshold;
- the impact of the COVID-19 coronavirus pandemic, including the spread of new strains of the virus, on our activities as described herein and otherwise, including but not limited to our ability to enroll a sufficient number of patients to advance our clinical trials;
- the therapeutic benefits, effectiveness and safety of our therapeutic candidates;
- the expected regulatory approval pathway for our therapeutic candidates and our ability to receive regulatory approval for our therapeutic candidates in the United States, Europe and other geographies;
- our reliance on third parties for the planning, conduct and monitoring of clinical trials for the manufacture of clinical drug supplies and drug product, and for other requirements;
- our dependance on contract research organizations and other institutions to manage our clinical trials;
- our ability to expand our therapeutic candidate portfolio through internal research and development or the acquisition or in-licensing of intellectual property assets;
- our ability to negotiate or renegotiate on favorable terms, or at all, agreements with third parties;
- our estimates of the size and characteristics of the markets that may be addressed by our therapeutic candidates;
- market acceptance of our therapeutic candidates that are approved for marketing in the United States or other countries;
- our ability to successfully commercialize our therapeutic candidates;
- the safety and efficacy of therapeutics marketed by our competitors that are targeted to indications which our therapeutic candidates have been developed to treat;
- the impact of natural disasters, global pandemics (including further outbreaks of existing strains of COVID-19 or new variants of the virus), armed conflicts and wars, labor disputes, lack of raw materials or other supplies, issues with facilities and equipment, or other forms of disruption to business operations at our manufacturing or laboratory facilities or those of our vendors or at clinical trial sites;
- our ability to utilize our proprietary technological approach to develop and commercialize our therapeutic candidates;

- potential collaborators to license and commercialize any therapeutic candidates for which we receive regulatory approval in the future in or outside of the United States;
- our heavy dependence on licensed intellectual property, including our ability to source and maintain licenses from third-party owners;
- our ability to protect our intellectual property and operate our business without infringing the intellectual property rights of others; and
- our ability to generate revenue and become profitable.

Factors that could cause actual results to differ materially from our expectations, assumptions and beliefs include, but are not limited to the following:

- exhausting available capital resources sooner than we expect;
- decisions by management in allocating our limited capital resources;
- grant awards not being made in the amount or at the time expected or at all;
- changes in the market that affect our ability to obtain financing and our exposure to credit risk;
- significant delay, scale back or discontinuation of the development or commercialization of one or more of our product candidates or a delay of our pursuit of potential licenses or acquisitions due to changes internally or to market conditions;
- failures in the design, conduct or outcome of our preclinical activities or trials or negative or inconclusive results;
- preclinical and clinical trials taking much longer than anticipated;
- competitors introducing technologies which render our development efforts or approved products obsolete;
- insufficient funding for internal research and development, partnerships or the acquisition or in-licensing of intellectual property assets;
- our reliance on third parties for the planning, conduct and monitoring of clinical trials and for the manufacture of clinical drug supplies and drug products;
- competitors realizing the full potential of a drug candidate before us;
- competitors successfully marketing products that are targeted to indications which our product candidates have been developed to treat;
- failure to become profitable or successfully commercialize due to a lack of safety, potency, purity and efficacy of any of our product candidates;
- inability to continue our operations at planned levels or a forced reduction or termination of our operations due to issues with clinicals or funding;
- an inability to raise additional capital on favorable terms or at all due to internal or market conditions;
- failure to accurately or timely report our financial conditions or results of operations;
- potential changes in regulatory requirements or delays or negative outcomes from the regulatory approval process;

- market acceptance of our product candidates that are approved for marketing in the United States or other countries;
- our heavy dependence on licensed intellectual property, including our ability to source and maintain licenses from third-party owners;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- future accounting pronouncements or changes in our accounting policies causing results to fluctuate significantly or fall below the expectations;
- our ability to attract, retain and motivate key personnel;
- the impact of natural disasters, global pandemics (including the outbreak of a novel strain of the COVID-19 coronavirus and subsequent spread of new strains of the virus), labor disputes, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations at our manufacturing facilities or clinical trial sites and the effectiveness of our precautions in protecting employee health and minimizing disruptions; and
- other risks and uncertainties, including those listed under the caption “Risk Factors” in our Annual Report on Form 10-K and in our other regulatory filings.

The risks set forth above are not exhaustive. Other sections of this Quarterly Report on Form 10-Q may include additional factors that could adversely affect our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for management to predict all risk factors, nor can we assess the impact of all risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in or implied by any forward-looking statements. Forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events and with respect to our business and future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under “Risk Factors” in our Annual Report on Form 10-K and in our other regulatory filings and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You are advised, however, to consult any further disclosures we make in our reports filed with the United States Securities and Exchange Commission, or SEC.

DATA, INFORMATION, TRADEMARKS, SERVICE MARKS, AND TRADE NAMES

This Quarterly Report on Form 10-Q may include data that we obtained from industry publications and third-party research, surveys and studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. This Quarterly Report on Form 10-Q also may include data based on our own internal estimates and research, including estimates regarding the impact of the COVID-19 pandemic (or related pandemic caused by coronavirus variants) on our financial performance and business operations. Our internal estimates have not been verified by any independent source and, while we believe any data obtained from industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Such third-party data, as well as our internal estimates and research, are subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors” in our Annual Report on Form 10-K and in our other regulatory filings and elsewhere in this Quarterly Report on Form 10-Q. These and other factors could cause our results to differ materially from those expressed in this Quarterly Report on Form 10-Q.

This Quarterly Report on Form 10-Q may contain trademarks, service marks and trade names of third-parties which are the property of their respective owners. Our use or display of third-parties’ trademarks, service marks, trade names or products in this Quarterly Report on Form 10-Q is not intended to, and does not, imply a relationship with such parties, or any endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this Quarterly Report on Form 10-Q may appear without the ®, TM or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

For the purpose of this Quarterly Report on Form 10-Q, TransCode Therapeutics® is referred to as TransCode. Additionally, “we,” “our,” “us” and the “Company” refer to TransCode.

REVERSE STOCK SPLIT

On May 23, 2023, the Company effected a reverse split of the Company’s common stock, shares either issued and outstanding or held by the Company as treasury stock, (the “2023 Reverse Split”). The 2023 Reverse Split was previously approved by the Board and shareholders of the Company. The 2023 Reverse Split was at a ratio of one share for every 20 shares previously held with no change in the par value per share. The 2023 Reverse Split did not change the number of authorized shares of common stock. All common stock share and per share data, and exercise price data for applicable common stock equivalents, included in this Quarterly Report on Form 10-Q, including our financial statements, have been retroactively adjusted to reflect the 2023 Reverse Split.

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

TRANSCODE THERAPEUTICS, INC.

BALANCE SHEETS

	June 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash	$ 3,572,475	$ 4,968,418
Grant receivable	—	360,229
Prepaid expenses and other current assets	1,320,462	2,050,758
Total current assets	4,892,937	7,379,405
Property and equipment, net of depreciation	178,975	208,581
Right-of-use asset	697,777	—
Security deposit	111,856	—
Total assets	$ 5,881,545	$ 7,587,986
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,044,042	$ 4,347,290
Deferred grant income	81,747	—
Current portion of lease liability	397,641	—
Total current liabilities	3,523,430	4,347,290
Long-term portion of lease liability	265,652	—
Total liabilities	3,789,082	4,347,290
Stockholders' equity (deficit):		
Preferred stock – $0.0001 par value; 10,000,000 shares authorized at June 30, 2023, and December 31, 2022; - 0- shares issued and outstanding at June 30, 2023, and December 31, 2022	—	—
Common stock – $0.0001 par value, 290,000,000 shares authorized at June 30, 2023, and December 31, 2022; 1,950,674 and 648,862 shares issued and outstanding at June 30, 2023, and December 31, 2022, respectively	195	65
Additional paid-in capital	39,121,104	31,110,880
Accumulated deficit	(37,028,836)	(27,870,249)
Total stockholders' equity	2,092,463	3,240,696
Total liabilities and stockholders' equity (deficit)	$ 5,881,545	$ 7,587,986

The accompanying notes are an integral part of these unaudited financial statements.

TRANSCODE THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 2,965,910	$ 2,620,028	$ 5,557,260	$ 4,501,604
General and administrative	2,164,926	2,087,265	4,474,688	3,683,191
Total operating expenses	5,130,836	4,707,293	10,031,948	8,184,795
Operating loss	(5,130,836)	(4,707,293)	(10,031,948)	(8,184,795)
Other income				
Grant income	788,937	34,730	868,345	41,720
Interest income	246	1,331	5,017	1,773
Total other income	789,183	36,061	873,362	43,493
Net loss	$ (4,341,653)	$ (4,671,232)	$ (9,158,586)	$ (8,141,302)
Basic and diluted loss per share				
Net loss	$ (4,341,653)	$ (4,671,232)	$ (9,158,586)	$ (8,141,302)
Weighted-average common shares outstanding	1,319,529	648,862	1,020,644	648,862
Net loss per share	$ (3.29)	$ (7.20)	$ (8.97)	$ (12.55)

The accompanying notes are an integral part of these unaudited financial statements.

TRANSCODE THERAPEUTICS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Six months ended June 30, 2023					
Balance, December 31, 2022	648,862	$ 65	$ 31,110,880	$ (27,870,249)	$ 3,240,696
Net loss	—	—	—	(4,816,934)	(4,816,934)
Issuances of common stock, net	142,315	14	1,180,672	—	1,180,686
Share based compensation	—	—	158,760	—	158,760
Balance, March 31, 2023	791,177	$ 79	$ 32,450,312	$ (32,687,183)	$ (236,792)
Net loss	—	—	—	(4,341,653)	(4,341,653)
Issuances of common stock, net	1,159,497	116	6,495,308	—	6,495,424
Share based compensation	—	—	175,484	—	175,484
Balance, June 30, 2023	1,950,674	$ 195	$ 39,121,104	$ (37,028,836)	$ 2,092,463
Six months ended June 30, 2022					
Balance, December 31, 2021	645,229	$ 65	$ 30,709,562	$ (10,305,281)	$ 20,404,346
Net loss	—	—	—	(3,470,070)	(3,470,070)
Exercise of stock options	3,633	—	5,989	—	5,989
Share based compensation	—	—	60,573	—	60,573
Balance, March 31, 2022	648,862	$ 65	$ 30,776,124	$ (13,775,351)	$ 17,000,838
Net loss	—	—	—	(4,671,232)	(4,671,232)
Share based compensation	—	—	98,599	—	98,599
Balance, June 30, 2022	648,862	$ 65	$ 30,874,723	$ (18,446,583)	$ 12,428,205

The accompanying notes are an integral part of these unaudited financial statements.

TRANSCODE THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (9,158,586)	$ (8,141,302)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	60,610	44,299
Amortization of right-of-use asset	177,180	—
Share-based compensation expense	334,244	159,172
Changes in assets and liabilities:		
Prepaid expenses and other current assets	730,296	1,458,646
Accounts payable and accrued expenses	(1,167,452)	(799,855)
Deferred grant income	81,747	(6,990)
Grants receivable	360,229	(34,730)
Security deposit	(111,856)	—
Operating lease liability	(211,664)	—
Net cash used in operating activities	(8,905,252)	(7,320,760)
Cash flows from investing activities:		
Purchase of equipment	(31,003)	(72,704)
Net cash used in investing activities	(31,003)	(72,704)
Cash flows from financing activities:		
Net proceeds from sales of common stock	7,676,109	—
Payments of deferred offering costs	(135,797)	—
Proceeds from exercise of stock options	—	5,989
Net cash provided by financing activities	7,540,312	5,989
Net change in cash	(1,395,943)	(7,387,475)
Cash, beginning of period	4,968,418	20,825,860
Cash, end of period	$ 3,572,475	$ 13,438,385
Supplemental disclosure of cash flow		
Cash paid during the period for:		
Interest related to insurance premium payment plan	$ 9,224	$ 5,129
Right-of-use assets obtained in exchange for operating lease liabilities	$ 874,957	$ —

The accompanying notes are an integral part of these unaudited financial statements.

TransCode Therapeutics, Inc.
Notes to Financial Statements
June 30, 2023
(Unaudited)

(1) Nature of Business and Liquidity

TransCode Therapeutics, Inc. (the "Company" or "TransCode") was incorporated on January 11, 2016, under the laws of the State of Delaware. TransCode is a biopharmaceutical company focused primarily on developing and commercializing innovative drugs and diagnostics for treating and identifying metastatic disease. TransCode is preparing for its first clinical trial. The Company's lead therapeutic candidate, TTX-MC138, is an oligonucleotide conjugated to an iron oxide nanoparticle designed to be administered by infusion to inhibit the ability of metastatic tumor cells to survive. The goal of the therapy, if approved, is to achieve lifelong regression and long-term patient survival.

From its founding until mid-2021, the Company was engaged in organizational activities, including raising capital, and limited research and development ("R&D") activities. On July 13, 2021, the Company completed the initial public offering ("IPO") of its common stock raising $28.75 million in gross proceeds. Since the IPO, the Company has increased its R&D activities, hired additional employees, and begun more traditional operations.

The Company has not generated revenues and has not yet achieved profitable operations, nor has it ever generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. The Company is subject to those risks associated with any early-stage biopharmaceutical company that requires substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approvals, or that any approved product will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees and consultants. Further, the Company's future operations are dependent on the success of the Company's efforts to raise additional capital.

Following the IPO, the Company's common stock commenced trading on the Nasdaq Capital Market under the ticker symbol "RNAZ". The Company issued 359,375 shares of common stock in connection with the IPO, including exercise of the underwriter's over-allotment option, at an initial offering price of $80.00 per share. The net proceeds from the IPO were approximately $25.4 million after deducting underwriting discounts, commissions and estimated offering expenses payable by the Company, including offering costs paid in 2020. In connection with the IPO, the Company also granted the underwriters warrants to purchase up to 15,625 shares of Company common stock at an exercise price of $100.00 per share (125% of the initial public offering price). Upon the closing of the IPO, outstanding convertible promissory notes converted into 53,406 shares of Company common stock.

Going Concern

These financial statements have been prepared under the assumption that the Company will continue as a going concern which contemplates the continuation of operations, realization of assets and liquidation of liabilities in the ordinary course of business. Due to the Company's recurring and expected continuing losses from operations, the Company has concluded there is substantial doubt concerning its ability to continue as a going concern within one year of the issuance of these financial statements without additional capital becoming available. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

To date, the Company has incurred substantial losses and negative cash flows from operations. It expects to continue to incur operating losses for the foreseeable future as it pursues development of its lead therapeutic candidate and other programs. Operating losses are expected to continue until such time, if ever, that the Company can generate significant revenue from product candidates currently in development. The Company is unable to predict the extent of any future losses or when the Company will become profitable, if ever.

For the six months ended June 30, 2023, net cash used in operating activities was $8.9 million and the Company's net loss was $9.2 million. As of June 30, 2023, the Company had an accumulated deficit of $37.0 million and $3.6 million in cash.

TransCode Therapeutics, Inc.
Notes to Financial Statements
June 30, 2023
(Unaudited)

The Company plans to expand development of its lead therapeutic candidate and other candidates, and explore strategic partnerships. Management believes that current cash is sufficient to fund operations and capital requirements into September 2023, but will not be sufficient to fund requirements for a full 12 months from the date of these financial statements.

To support its planned expanded operations, the Company will require additional capital; however, the Company cannot be certain that additional funding will be available on acceptable terms, or at all. Through June 30, 2023, the Company's primary source of capital was from the sale of equity securities, funds received under the SBIR Award (see Note 7), and previous sales of convertible promissory notes. For the foreseeable future, the Company plans to fund its operations by continuing to raise additional capital, primarily through sales of equity or debt and pursuit of additional grants.

To the extent the Company raises additional funds by issuing equity securities, its stockholders may experience significant dilution. Any debt financing, if available, may include potentially dilutive features and include restrictive covenants that impact the Company's ability to conduct business. If the Company is unable to raise additional capital when required or on acceptable terms, the Company may have to (i) significantly scale back its planned operations or (ii) relinquish or otherwise dispose of rights to technologies on unfavorable terms.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation

These financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). In the opinion of management, these financial statements include all adjustments, consisting only of normal, recurring adjustments, necessary for a fair presentation of the financial position of TransCode Therapeutics, Inc. at June 30, 2023, and its results of operations for the three and six months ended June 30, 2023 and 2022, and its cash flows for the six months ended June 30, 2023 and 2022. The interim results of operations are not necessarily indicative of the results to be expected for a full year. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2022, and notes thereto contained in the Company's Annual Report on Form 10-K, filed with the SEC. Certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to such rules and regulations relating to interim financial statements.

(b) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and liabilities, at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant items subject to such estimates and assumptions include but are not limited to the valuation of share-based compensation, income from grants, and accrued research and development costs. Future events and their effects cannot be predicted with certainty; accordingly, accounting estimates require the exercise of judgment. Accounting estimates used in the preparation of these financial statements change as new events occur, as more experience is acquired, as additional information is obtained and as the operating environment changes. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the financial statements, actual results may materially vary from these estimates.

TransCode Therapeutics, Inc.
Notes to Financial Statements
June 30, 2023
(Unaudited)

(c) Basic and Diluted Earnings (Loss) per Share

Basic net loss per share is determined by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share includes the effect, if any, from the potential conversion, vesting or exercise of securities (Contingent Securities) such as convertible promissory notes, stock options and warrants, which would result in the issuance of additional shares of common stock. The computation of diluted net loss per shares does not include the conversion or exercise of Contingent Securities when the effect of doing so would be antidilutive.

(d) Cash

The Company classifies deposits in banks, money market funds and cash invested temporarily in various instruments with original maturities of three months or less as cash and cash equivalents. To date, the Company has not held any funds in money market funds or instruments with original maturities of three months or less. The Company holds significant cash balances in U.S. banks which throughout the year regularly exceed the federally insured limit of $250,000. Any loss incurred or lack of access to such funds could have a material adverse effect on the Company's financial condition, results of operations, and cash flows.

(e) Fair Value of Financial Instruments

The Company's financial instruments at June 30, 2023, and December 31, 2022, included cash, grant receivable, prepaid expenses and other current assets, right-of-use asset, accounts payable and accrued expenses, deferred grant income, and current and long-term portion of lease liability. Cash is reported at fair value. The recorded carrying amount of grant receivable, prepaid expenses and other current assets, accounts payable and accrued expenses, deferred grant income, and current and long-term portion of lease liability approximate their fair value due to their short-term or fixed arrangements nature.

(f) Research and Development

Research and development costs are expensed as incurred and primarily comprise expenses to discover, research and develop therapeutic candidates. These expenses may include personnel costs, stock-based compensation expense, materials and supplies, allocated facility-related and depreciation expenses, third-party license fees, and costs under arrangements with third party vendors, such as contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and consultants. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as expenses as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

The Company has entered into various research and development-related contracts with companies both inside and outside the United States. The related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates.

Patent Costs

All legal fees and expenses and costs related to patent-related filings with governmental authorities incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses. Other patent costs are classified as R&D expenses.

TransCode Therapeutics, Inc.
Notes to Financial Statements
June 30, 2023
(Unaudited)

(g) Grant Income

Funds from grants are recognized as grant income in the statements of operations as and when earned for the specific research and development projects for which the grants are designated. In April 2021, the Company received an award (the "Award") from the National Cancer Institute in support of the Company's lead therapeutic candidate. Since there is no transfer of ownership of the work performed under the Award, and the Company does not lose control over the work performed under the Award, the Company deems the Award funds as a contribution. Grant payments received in excess of grant income earned are recorded as deferred grant income on the Company's balance sheet until the related income has been earned. Grant income earned in excess of grant payments received is recorded as grant receivable on the Company's balance sheet.

(h) Share-Based Compensation

Share-based compensation, if any, for employees and non-employees is measured at the grant date based on the fair value of the award. The Company recognizes compensation expense, if any, for awards to employees and directors over the requisite service period, which is generally the vesting period of the respective award, and for awards to non-employees over the period during which services are rendered by such non-employees until completed. Generally, the Company issues awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company classifies share-based compensation expense in its statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified. Forfeitures are accounted for as they occur.

Because prior to the IPO, there was no public market for the Company's common stock, the estimated fair value of the common stock was determined by the Company's board of directors (the "Board") as of the date of each award, with input from management, considering, when available, third-party valuations of the Company's common stock as well as the Board's assessment of additional objective and subjective factors that it believed were relevant and which may have changed between the date of the then most recent third-party valuation, if any, and the date of the grant. The assumptions used in calculating the fair value of share-based awards represented management's best estimates and involved inherent uncertainties and the application of management's judgment. As a result, if factors were to change and management were to use different assumptions, share-based compensation expense could be materially different. The fair value of awards made subsequent to the IPO are determined using the closing price of the Company's common stock on the date of grant.

Certain stock appraisal methodologies utilize, among other variables, the volatility of the stock price. When private, the Company lacked Company-specific historical and implied volatility information for its stock. Therefore, it estimated its expected stock price volatility based on the historical volatility of publicly-traded peer companies and expects to continue to do so until such time, if ever, as it has adequate historical data regarding the volatility of its own publicly-traded stock price. The expected life of options awarded was estimated using the simplified method because the Company has limited historical information on which to base reasonable expectations about future exercise patterns and post-vesting employment. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on its common stock and does not expect to pay cash dividends in the foreseeable future.

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(i) Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated useful life
Laboratory equipment	3 years
Furniture and fixtures	5 years
Computer and office equipment	3 years
Leasehold improvements	Shorter of the useful life or remaining lease term

When assets are retired or otherwise disposed of, the cost of assets disposed of and the related accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the statements of operations in the period of disposal. Expenditures for repairs and maintenance are charged to expense as incurred.

(j) Income Taxes

The Company provides for income taxes using the asset and liability approach. Deferred tax assets and liabilities are recorded based on the differences between the financial statement and tax bases of assets and liabilities and the tax rates in effect when these differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of the dates of the Company's balance sheets herein, the Company had a full valuation allowance against deferred tax assets.

The Company is subject to the provisions of ASC 740-10-25, "Income Taxes" (ASC 740). ASC 740 prescribes a more likely-than-not threshold for the financial statement recognition of uncertain tax positions. ASC 740 clarifies the accounting for income taxes by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

There are currently no open federal or state tax audits. The Company has not recorded any liability for uncertain tax positions at the dates of the Company's balance sheets herein.

(k) Emerging Growth Company Status

The Company is an "emerging growth company" ("EGC") as defined in the Jumpstart Our Business Startups Act ("JOBS Act") and may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act and has elected to use the extended transition period for complying with new or revised accounting standards. As a result of this election, the Company's financial statements may not be comparable to companies that comply with public company FASB standards' effective dates. The Company may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of a public offering or such earlier time that it is no longer an EGC.

(l) Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40) ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The ASU is part of the FASB's simplification initiative, which aims to reduce unnecessary complexity in U.S. GAAP. The ASU's amendments are effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. The Company's adoption of ASU 2020-06 on January 1, 2023, did not have a material impact on the Company's financial statements.

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(m) Reverse Stock Split

On May 23, 2023, the Company effected a reverse split of the Company's common stock, either issued and outstanding or held by the Company as treasury stock, (the "2023 Reverse Split") previously approved by the Board and shareholders of the Company. The 2023 Reverse Split was at a ratio of one share for every 20 shares previously held with no change in the par value per share. The 2023 Reverse Split did not change the number of authorized shares of common stock. All common stock share and per share data, and exercise price data for applicable common stock equivalents, included in these financial statements have been retroactively adjusted to reflect the reverse stock split.

(n) Collaboration Agreements

When the Company enters into a collaboration agreement, it evaluates the arrangement against the requirements of Accounting Standards Codification (ASC) 808 Collaborative Arrangements ("ASC 808") as well as Accounting Standards Update 2018-18 which clarifies the interaction between Topic 808 and Topic 606 (ASU 2018-18). ASU 2018-18 indicates that collaborative arrangements could be partially in the scope of other guidance, including ASC 606.

(o) Leases

The Company leases certain office and laboratory space. At inception, the Company determines if a contract or arrangement contains a lease. Leases are evaluated and classified as either operating or finance leases. A lease is classified as a finance lease if any of the following criteria are met: (i) ownership of the underlying asset transfers to the Company by the end of the lease term; (ii) the lease contains an option to purchase the underlying asset that the Company is reasonably expected to exercise; (iii) the lease term is for a major part of the remaining economic life of the underlying asset; (iv) the present value of the sum of lease payments and any residual value guaranteed by the Company equals or exceeds substantially all of the fair value of the underlying asset; or (v) the underlying asset is of a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. A lease that does not meet any of the criteria to be classified as a finance lease is classified as an operating lease. Operating leases are included on the balance sheets as Right-of-Use (ROU) assets, net; Current portion of operating lease liabilities; and Operating lease liabilities. ROU assets and operating lease liabilities are recognized based on the present value of the future lease payments over the lease term at the commencement date. Where leases do not provide an implicit rate for use in determining the present value of future payments, the Company uses an incremental borrowing rate that represents the cost of borrowing on a collateralized basis for a period equal to the expected lease term. ROU assets also include any lease payments made and exclude any lease incentives and initial direct costs incurred. Lease terms may include periods under options to extend the lease or terminate the lease prior to expiration when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term, including rent abatement periods and rent holidays. While lease liabilities are not remeasured as a result of changes to these costs, changes are treated as variable lease payments and recognized in the period in which the obligation for those payments was incurred. Finance leases are included on the balance sheets as Property and Equipment, net; Current maturities of long-term debt; and Long-term debt. Finance lease costs are split between depreciation expense related to the asset and interest expense on the lease liability, using the effective rate charged by the lessor. The Company has elected to account for lease and non-lease components separately. Additionally, the Company has elected not to record short-term leases, those with expected terms of twelve months or less, on the balance sheets. Certain lease agreements include fixed escalations, while others include rental payments adjusted periodically for inflation.

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(3) Fair Value Measurements

ASC 820, “Fair Value Measurements”, provides guidance on the development and disclosure of fair value measurements. The Company follows this guidance for fair value measurements, which defines fair value, establishes a framework for measuring fair value under U.S. GAAP, and expands disclosures about fair value measurements. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities.

Level 2: Observable prices that are based on inputs not quoted on active markets but corroborated by market data.

Level 3: Unobservable inputs which are supported by little or no market activity with values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Fair value measurements discussed herein are based upon certain market assumptions and pertinent information available to management as of the dates of the Company’s balance sheets herein. The carrying amount of cash, grant receivable, prepaid expenses and other current assets, right-of-use asset, accounts payable and accrued expenses, deferred grant income, and current and long-term portion of lease liability approximate their fair value due to their short-term or fixed arrangements nature.

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	June 30, 2023	December 31, 2022
Prepaid operating expenses	$ 138,415	$ 122,428
Contract manufacturers and research organizations	722,347	241,111
Insurance premiums	37,208	1,255,317
Prepaid FICA	422,492	422,492
Deposits	—	9,410
	$ 1,320,462	$ 2,050,758

(5) Property and Equipment

Property and equipment, net consisted of the following:

	June 30, 2023	December 31, 2022
Laboratory and computer equipment	$ 379,444	$ 348,441
Less accumulated depreciation	(200,469)	(139,860)
Total property and equipment, net	$ 178,975	$ 208,581

Depreciation expense for the three months ended June 30, 2023 and 2022, was $30,970 and $22,698, respectively, and $60,610 and $44,299, respectively, for the six months ended June 30, 2023 and 2022.

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(6) Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	June 30, 2023	December 31, 2022
Professional and general consulting fees	$ 317,089	$ 758,816
R&D expenses – CMOs, CROs, supplies, equipment and consulting	1,904,658	2,397,038
General expenses	464,808	124,676
Insurance premiums	3,217	844,283
Payroll and benefits	312,242	164,657
Accrued license payments	42,028	57,820
	$ 3,044,042	$ 4,347,290

At June 30, 2023, and December 31, 2022, the Company's outstanding payables to CROs or CMOs included above were $1,524,945 and $2,030,347, respectively.

See Note 8 for further information regarding the accrued license payments.

(7) Grant Income

In April 2021, the Company received a Fast-Track Small Business Innovation Research Award (the "SBIR Award") from the National Cancer Institute of the National Institutes of Health (the "NIH"). The Award was for up to $2,392,845 over three years to fund a two-phased research partnership between the Company and Massachusetts General Hospital. In May 2021, the Company received the first year funding of $308,861. In May 2022, second-year funding of $1,129,316 was made available to the Company. In April 2023, the Company received funding of $870,684 for the third year of the SBIR Award. Income under the grant is recognized as work under the grant is completed. The Company recognized grant income of $788,937 and $868,345, respectively, for the three and six months ended June 30, 2023, and $34,730 and $41,720, respectively, for the three and six months ended June 30, 2022. The Company had deferred grant income of $81,747 and $0 at June 30, 2023, and December 31, 2022, respectively.

(8) Commitments and Contingencies

(a) Leases

In March 2021, the Company entered into an agreement with Massachusetts Biomedical Initiatives, Inc. ("MBI") whereby the Company subleased approximately 2,484 square feet of laboratory space with room for minor administrative functions. The Company was also permitted to use shared laboratory equipment at the facility. The monthly rental was $6,521 and the Company paid an additional amount for its allocated share of operating expenses, which in 2022 was $3,105 per month. In 2022, the Company added the right to use cubicle space outside its laboratory area to its sublease for an additional $650 per month, resulting in total monthly rental of $10,276. The sublease terminated as of February 2023.

Operating Lease

In December 2022, the Company signed an agreement to sublease 4,837 square feet of laboratory and office space in Newton, Massachusetts, from another biopharmaceutical company. The Company considers this sublease an operating lease with estimated right-of-use (ROU) assets and lease liabilities of approximately $0.9 million recorded upon lease commencement on February 1, 2023. The sublease has a term of 24 months, and the Company has the option to extend the sublease for an additional 12 months. The Company does not believe that the exercise of this option is probable so has not included it in determination of the lease amounts. The base monthly rent is $37,285 during the first 12 months of the lease, $38,403 in the second 12 months, and, if the Company exercises the option to extend the lease, $39,559 in the third 12-month period. In addition, the Company is responsible for its share of operating expenses, real estate taxes, and utilities based on the actual costs of these items.

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The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating lease for the six months ended June 30, 2023. Prior to February 1, 2023, the Company had no operating leases with maturities greater than one year. The Company does not recognize any variable lease costs or short-term lease costs in connection with the operating lease.

Operating Leases	Six Months Ended June 30, 2023
Weighted average remaining lease term (years)	1.58
Weighted average discount rate	3.6 %
Year ending December 31,	
2023	$ 186,426
2024	459,749
2025	38,291
Total undiscounted lease payments	684,466
Imputed interest	(21,173)
Lease liability	$ 663,293

Rent expense for the three months ended June 30, 2023 and 2022, was $188,906 and $103,161, respectively, and $337,881 and $143,590, respectively, for the six months ended June 30, 2023 and 2022.

(b) License Agreements

In November 2018, the Company licensed the exclusive rights to certain intellectual property to support development of its therapeutic candidates ("License"). The intellectual property licensed by the Company is owned by The General Hospital Corporation, d/b/a Massachusetts General Hospital, ("Licensor"). Payments by the Company under the license agreement included a one-time non-refundable fee of $50,000 paid after execution of the License; reimbursement of Licensor's patent costs which, at execution of the License, were approximately $145,000; a minimum annual license fee of $25,000 payable within 60 days of each anniversary of the effective date of the License prior to the first commercial sale of a product or process covered by the License; milestone payments upon attainment of certain milestone events; royalties based on net sales of products covered by the patent-related rights; and a portion of any sublicense income received by the Company. The Company is responsible for the development and commercialization of the licensed assets and for meeting certain milestones set forth in the License.

The milestone payments the Company shall pay to Licensor shall not exceed $1,550,000 based upon and subject to the attainment of each milestone event indicated below. These payments are generally due within 60 days of achievement of the milestone.

Milestone Event	Amount
Enrollment of first patient in a phase II clinical trial of a therapeutic product or process	$ 100,000
Enrollment of first patient in a phase III clinical trial of a therapeutic product or process	$ 200,000
First commercial sale of a therapeutic product or process	$ 1,000,000
Filing of an application for regulatory approval of a clinical diagnostic product or process	$ 100,000
First regulatory approval of a clinical diagnostic product or process	$ 150,000

As of June 30, 2023, and December 31, 2022, no milestone events had been achieved.

The royalties to be paid to Licensor shall be assessed on net sales of licensed products on a country-by-country basis in an amount equal to 3.0% for therapeutic products or processes, and 6.0% for clinical diagnostic products and processes. The Company shall pay Licensor 30% of any and all sublicense income.

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The Company has the right to terminate the License at any time by giving 90 days advance notice subject to the payment of any amounts due under the License at that time. The License may also be terminated for cause by either party upon the breach of the material obligations of the other party or the bankruptcy or liquidation of the other party. If the Company does not terminate the License, the term of the License shall continue until the latest of (i) the date on which all issued patents and filed patent applications subject to the License have expired or been abandoned; (ii) expiration of the last to expire regulatory exclusivity covering a covered product or process; or (iii) 10 years after the first commercial sale. The License requires the Company to make royalty payments beyond the term of the License at 1.5%.

In November 2020, the Company and Licensor amended the November 2018 license. Under the amendment, the intellectual property licensed in 2018 was categorized as “Patent Family 1” and a provisional patent filing related to the Company’s nanoparticle technology was added to Patent Family 1. A second patent family (“Patent Family 2”) was created which includes Licensor intellectual property targeting PD-L1.

The minimum annual license fee prior to the first commercial sale of a product or process covered by the License was increased from $25,000 per year to $30,000 per year for Patent Family 1 and a minimum annual license fee of $10,000 per year was added related to Patent Family 2. All other terms of the License including milestone payments, royalties and payment terms related to sublicense income received by the Company remain the same as in the original License.

Option Agreement – Radiolabeled Nanoparticles

The Company signed an Exclusive Option Agreement (the “Radiolabeled Option”) with the Licensor effective April 15, 2022. Under the Radiolabeled Option, the Company has the exclusive right to negotiate a license of technology patented by the Licensor pertaining to Therapeutic, Radiolabeled Nanoparticles and Methods of Use Thereof, described and claimed in Patent Application PCT/US2021/057912. The Radiolabeled Option provides for a one-year term at a cost of $7,500 with a right to extend, upon the mutual agreement of the parties, for an additional six months for an additional payment of $5,000. The Company is also responsible for patent costs related to the subject technology incurred by Licensor during the Radiolabeled Option period. Patent costs incurred by the Licensor prior to the effective date will not be reimbursed.

Accrued License Obligations

At June 30, 2023, and December 31, 2022, the Company had accrued $42,028 and $57,820, respectively, in license payments under the foregoing arrangements included in accounts payable and accrued expenses.

(c) Collaboration Agreement

On July 29, 2022, the Company signed a five-year strategic collaboration agreement with The University of Texas M. D. Anderson Cancer Center (“MD Anderson”). Under the collaboration, the Company anticipates making certain expenditures with respect to Phase I and Phase II clinical trials in part through MD Anderson as a primary investigator site. MD Anderson will also provide preclinical work under the collaboration. The details of clinical and preclinical work are to be mutually agreed by the parties prior to commencing work. The Company has committed to fund up to $10 million over the term of the collaboration. Of this amount, the initial payment schedule called for $500,000 to be paid within the first year. Subsequent payments were scheduled to be $2 million on the first anniversary of the effective date of the agreement and $2.5 million on each of the second, third and fourth anniversaries thereof. The Company is currently in negotiations with MD Anderson regarding committed upcoming payments as a result of changes in personnel at MD Anderson and in planned work. There is no assurance regarding the outcome of discussions with MD Anderson. Payments to MD Anderson are initially recorded as Prepaid Expenses. As work under the collaboration is performed by MD Anderson, the Company records research and development costs in its Statements of Operations. Total expenses incurred under the arrangement for the three and six months ended June 30, 2023 and 2022, were $0 in all periods. The arrangement expires on the later of July 29, 2027, or when the last active study is completed.

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(d) Employment Agreements

Prior to the IPO, the Company entered into employment agreements with its executive officers which became effective on completion of the IPO. The employment agreements provide the employee with, among other things, severance payments upon termination of the agreement by the Company for any reason other than for cause, death or disability or by the employee for good reason. The maximum aggregate severance payments under the agreements, which arise in the event of termination involving a Change of Control (as defined in the agreements), are approximately $2,483,700.

(e) Litigation

The Company may from time to time be subject to claims by others under various legal disputes. The defense of such claims, or any adverse outcome relating to any such claims, could have a material adverse effect on the Company's liquidity, financial condition, and cash flows. At June 30, 2023, and December 31, 2022, the Company did not know of any claims or actions pending against us or threatened, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

(f) Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and executive officers that require the Company, among other things, to indemnify the parties against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any costs as a result of payments required by such indemnifications. The Company is not aware of any indemnification arrangements that could have a material adverse effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements, as of June 30, 2023, and December 31, 2022.

(g) Risks and Uncertainties

As SARS-CoV-2, or the coronavirus, continues to evolve, the extent to which it affects the Company's operations directly or through parties on whom the Company depends is highly uncertain and cannot be predicted with confidence. The outcomes resulting from these events could delay the Company's plans, increase its operating expenses and have a material adverse effect on its financial condition or results of operations.

(9) Stockholders' Equity

(a) Overview

The Company's Certificate of Incorporation, originally filed on January 11, 2016, was amended on April 15, 2020, to increase the number of shares of common stock authorized and to authorize the issuance of preferred stock. The Company's Certificate of Incorporation was further amended and restated on April 27, 2021, and on May 22, 2023, to effect the 2023 Reverse Split. The total number of shares which the Company is authorized to issue is 300,000,000, each with a par value of $0.0001 per share. Of these shares, 290,000,000 shall be common stock and 10,000,000 shall be preferred stock. At June 30, 2023, and December 31, 2022, the Company had 1,950,674 and 648,862 shares of common stock issued and outstanding, respectively. The preferred stock is undesignated; no shares of preferred stock have been issued.

On February 16, 2023, the Company entered into a Securities Purchase Agreement with certain purchasers named therein pursuant to which the Company sold 142,315 shares of common stock in a registered direct offering at a purchase price of $10.54 per share (the "February RDO"). Net proceeds from the February RDO, after deducting fees payable to the placement agent and other

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offering expenses, were approximately $1.2 million. In connection with the February RDO, the Company also issued the placement agent warrants to purchase up to 9,962 shares of common stock (the "Placement Agent Warrants"). The Placement Agent Warrants will be exercisable commencing six months following the date of issuance, expire five years following the date of sale and have an exercise price per share of $13.175. See Note 10.

In April and May 2023, the Company sold an aggregate of 110,000 shares to White Lion Capital LLC ("White Lion") under a Common Stock Purchase Agreement dated April 14, 2023, (the "White Lion Purchase Agreement") between the Company and White Lion. Net proceeds to the Company were $518,844 after White Lion expenses but before aggregate legal and printing expenses the Company incurred of $75,418. The commitment period ended May 31, 2023.

On June 6, 2023, the Company entered into a Securities Purchase Agreement with a purchaser named therein pursuant to which the Company sold 99,000 shares of common stock, 1,901,000 pre-funded warrants ("PFWs"), together with accompanying 2,000,000 Series A-1 Warrants to purchase common stock (the "Series A-1 Warrants"), and 2,000,000 Series A-2 Warrants to purchase common stock (the "Series A-2 Warrants") in a registered direct offering at a purchase price of $3.50 per share or PFW (the "June RDO"). The Series A-1 Warrants and the Series A-2 Warrants are identical in all material respects. The Series A -1 Warrants and Series A-2 Warrants became exercisable commencing June 9, 2023, and are exercisable for three years at an exercise price of $3.25 per share. Net proceeds from the June RDO, after deducting fees payable to the placement agent and other offering expenses, were approximately $6.1 million.

In connection with the June RDO, the Company also issued the placement agent warrants to purchase up to 140,000 shares of common stock (the "June Placement Agent Warrants"). The June Placement Agent Warrants became exercisable commencing June 9, 2023, expire three years following the date of sale and have an exercise price per share of $4.375. See Note 10.

(b) Common Stock

i. Dividends

Subject to the rights of holders of any preferred stock, holders of common stock are entitled to receive dividends as may be declared from time to time by the Board. No cash dividends were declared or paid during the three and six months ended June 30, 2023, nor at any other time through the date of these financial statements.

ii. Liquidation

Subject to the rights of holders of any preferred stock as to liquidation, upon the liquidation, dissolution or winding up of the Company, the remaining assets of the Company will be distributed to holders of common stock.

iii. Voting

Holders of common stock are entitled to one vote for each share of common stock held but shall not be entitled to vote on any amendment to the Certificate of Incorporation that relates solely to the terms of any series of preferred stock. There is no cumulative voting.

(10) Warrants

In connection with the IPO, the Company granted the underwriters warrants to purchase up to 15,625 shares of Company common stock at an exercise price of $100.00 per share, which amount is 125% of the initial public offering price. The warrants have a five-year term and were not exercisable prior to January 9, 2022. All of the warrants were outstanding at June 30, 2023. The Company accounts for the warrants as a component of stockholders' equity.

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In connection with the February RDO, the Company issued the placement agent warrants to purchase up to 9,962 shares of common stock. The Placement Agent Warrants become exercisable commencing August 17, 2023, expire February 16, 2028, and have an exercise price per share of $13.175 per share.

In connection with an agreement the Company entered into with a consultant in February 2023, the Company agreed to issue warrants to purchase up to 12,500 shares of common stock at $10.00 per share. These warrants were to be exercisable any time after August 23, 2023, until February 23, 2028, subject to the Company's right in its sole discretion exercisable not later than August 22, 2023, to reduce the number of warrants to 6,250. The Company exercised this right in May 2023.

In connection with the June RDO, the Company issued 1,901,000 PFWs, together with accompanying 2,000,000 Series A-1 Warrants and 2,000,000 Series A-2 Warrants, at a purchase price of $3.49 per PFW. Each PFW is exercisable at $0.01 per share. The PFWs do not terminate or expire. The Series A-1 Warrants and Series A-2 Warrants became exercisable commencing June 9, 2023, expire three years following the date of sale and have an exercise price of $3.25 per share. The Company also issued the placement agent warrants to purchase up to 140,000 shares of common stock. The June Placement Agent Warrants became exercisable commencing June 9, 2023, expire three years after issuance, and have an exercise price per share of $4.375 per share.

The following table summarizes the Company's outstanding or issuable warrants at June 30, 2023:

Description	Number of Shares	Exercise Price Per Share
Placement agent warrants from IPO	15,625	$ 100.00
Placement agent warrants from February RDO	9,962	13.18
Consultant warrants	6,250	10.00
Series A-1 warrants	2,000,000	3.25
Series A-2 warrants	2,000,000	3.25
Placement agent warrants from June RDO	140,000	4.38
Pre-funded warrants from June RDO	950,000	0.01

(11) Share-Based Compensation

In April 2020, the Board approved the TransCode Therapeutics, Inc. 2020 Stock Option and Incentive Plan (the "2020 Plan") providing for the issuance of options or other awards to purchase up to 151,639 shares of the Company's common stock. The Board determined not to make any further awards under the 2020 Plan following the closing of the IPO. In March 2021, the Company's 2021 Stock Option and Incentive Plan (the "2021 Plan") was approved by the Company's Board and stockholders and became effective upon the effectiveness of the IPO. The 2021 Plan initially provided for the issuance of options or other awards to purchase up to 125,000 shares of the Company's common stock. The number of options or other awards available under the 2021 Plan increased 32,261 shares in January 2022 and 32,443 in January 2023.

Both Plans provide for grants of equity in the form of stock awards, stock options and other instruments to employees, members of the Board, officers and consultants of and advisors to the Company. The Plans are administered by the Board or, at the discretion of the Board, by a committee of the Board. The amount and terms of grants are determined by the Board. The terms of options granted under the Plans generally are for ten (10) years after date of grant and are exercisable in cash or as otherwise determined by the Board. The vesting period for equity-based awards is determined at the discretion of the Board and is generally two to four years. If stock options granted under the 2021 Plan terminate, expire, or are surrendered or cancelled, the shares subject to such grants will again be available under the 2021 Plan.

The exercise price for incentive stock options is determined at the discretion of the Board but for grants to any person possessing less than 10% of the total combined voting power of all classes of stock may not have an exercise price less than 100% of the fair market value of the Common Stock on the grant date (110% for grants to any person possessing more than 10% of the total combined voting power of all classes of stock). The option term for incentive stock option awards may not be greater than ten years from the

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date of the grant (five years for grants to any person possessing more than 10% of the total combined voting power of all classes of stock).

In 2020, the Board awarded options to purchase 87,813 shares of common stock under the 2020 Plan. In 2021, the Board awarded options to purchase 1,819 shares of common stock under the 2020 Plan. Of the options issued under the 2020 Plan, options for 3,948 shares terminated in December 2021 and options for 3,633 shares were exercised in January 2022. In 2022 and 2023, the Board awarded options to purchase common stock under the 2021 Plan as follows:

Date	Number of Options	Exercise Price Per Share
February 2022	12,950	$ 49.00
March 2022	9,700	$ 42.40
June 2022	1,425	$ 24.80
October 2022	12,125	$ 21.40
December 2022	32,600	$ 10.20
May 10, 2023	1,425	$ 5.97
May 19, 2023	115,000	$ 5.67

Of options awarded under the 2021 Plan, 185,225 were outstanding at June 30, 2023.

At June 30, 2023, there were 76,378 options outstanding under the 2020 Plan that were vested and exercisable and 8,820 options outstanding under the 2021 Plan that were vested and exercisable. Information about options to purchase common stock of the Company under both Plans is as follows:

	Number of shares	Weighted average exercise price per share	Weighted average contractual term (years)
Outstanding at December 31, 2021	85,685	$ 6.60	5.2
Granted	68,800	24.40	6.4
Exercised	(3,633)	1.60	—
Forfeited	—	—	—
Outstanding at December 31, 2022	150,852	14.80	5.3
Granted	116,425	5.67	0.9
Exercised	—	—	—
Forfeited	—	—	—
Outstanding at June 30, 2023	267,277	$ 10.84	4.9

The intrinsic value of the outstanding options as of June 30, 2023, was $0.

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Option valuation

The assumptions that the Company used to determine the grant-date fair value of options granted in the six months ended June 30, 2023 and 2022, were as follows:

	Six months ended June 30,	
	2023	2022
Risk-free interest rate	4.01% - 4.72%	1.38% - 2.79%
Expected term (in years)	6.0	3.5 - 6.0
Expected volatility	100.6% - 100.8%	93.2%
Expected dividend yield	—	—
Fair value per share of underlying stock	$5.67 - $5.97	$24.80 - $49.00

The weighted average grant date fair value per share of the options granted in the six months ended June 30, 2023 and 2022, was $4.59 and $34.00, respectively.

The Company recorded share-based compensation expense of $175,484 and $334,244 during the three and six months ended June 30, 2023, respectively, and $98,599 and $159,172 during the three and six months ended June 30, 2022, respectively, all of which related to stock options. The remaining share-based compensation expense to be recognized in the future is approximately $1,449,755 over approximately 2.2 years.

(12) Employee Stock Purchase Plan

In 2021, the Company adopted an Employee Stock Purchase Plan (the “ESPP”) to provide eligible employees of the Company with opportunities to purchase shares of the Company’s common stock. The ESPP initially provided for the purchase of an aggregate of up to 7,500 shares of common stock. The number of shares of common stock available through the ESPP increased by 4,500 shares in January 2022 and January 2023, and may be increased each subsequent year by up to 4,500 shares.

(13) Net Loss Per Share

The Company reported net losses for the three and six months ended June 30, 2023 and 2022. Reported basic and diluted net loss per share attributable to common stockholders are the same for all periods because shares issuable in connection with Contingent Securities have been excluded from the computation of diluted weighted-average shares outstanding. As indicated in the table below, the effect of their inclusion would have been antidilutive.

In accordance with ASC 260-10-45-13, a penny warrant is an instrument that requires the holder to pay little or no consideration to receive the shares upon exercise of the warrant. Since the shares underlying the PFWs are issuable for little or no consideration, the Company considered them outstanding in the context of basic earnings per share.

The following table sets forth the computation of basic and diluted loss per share:

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Basic and diluted loss per share				
Net loss	$ (4,341,653)	$ (4,671,232)	$ (9,158,586)	$ (8,141,302)
Weighted-average common shares outstanding	1,319,529	648,862	1,020,644	648,862
Net loss per share	$ (3.29)	$ (7.20)	$ (8.97)	$ (12.55)

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Shares issuable upon the exercise of stock options shown in the computation of diluted loss per weighted-average share outstanding are assumed as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Shares issuable on exercise of vested options	92,015	41,248	92,015	41,248

(14) Income Taxes

The Company's income tax benefit (expense) was $0 for the three and six months ended June 30, 2023 and 2022. The Company has recorded a full valuation allowance against its net deferred tax assets as of June 30, 2023, and December 31, 2022, because the Company has determined that is it more likely than not that these assets will not be fully realized due to historic net operating losses incurred. Accordingly, the benefit of the net operating loss that would have been recognized in the three and six months ended June 30, 2023 and 2022, was fully offset by changes in the valuation allowance.

As of June 30, 2023, and December 31, 2022, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations.

(15) Subsequent Events

For its financial statements as of June 30, 2023, the Company evaluated subsequent events through August 14, 2023, the date on which those financial statements were issued and determined that there were none for which disclosure is warranted.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Note Regarding Forward-Looking Statements

Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," "will," or "would," and/or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors, including those set forth in the "Risk Factors" section included in our Annual Report on Form 10-K for the year ended December 31, 2022, that may cause our actual results, levels of activity, performance or achievements to be materially different from the results described in or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us, and our expectations of the future, about which we cannot be certain.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements described in the section of this Quarterly Report on Form 10-Q entitled "CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS."

You should refer to "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Those factors are updated, as applicable, in "Factors that May Affect Future Results" below. As a result of the risks, uncertainties and assumptions described above and elsewhere, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to new information, actual results or changes in our expectations.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with: (i) the interim financial statements and related notes thereto which are included in this Quarterly Report on Form 10-Q; and (ii) our annual financial statements for the year ended December 31, 2022, which are included in our Annual Report on Form 10-K for the year ended December 31, 2022.

Company Overview

TransCode is a platform delivery company focused on oncology, created on the belief that cancer can be defeated through the intelligent design and effective delivery of targeted therapeutics. Our lead therapeutic candidate, TTX-MC138, targets microRNA-10b, or miRNA-10b, a master regulator of metastatic cell viability in a range of cancers, including breast, pancreatic, ovarian, colon cancer, glioblastomas, and several others. In December 2022, TransCode received authorization from the U.S. Food and Drug Administration, or FDA, to conduct a Phase 0 clinical trial intended to demonstrate quantitative delivery of TTX-MC138 to metastatic lesions in subjects with advanced solid tumors. On April 25, 2023, we received Institutional Review Board, or IRB, approval from the Dana Farber Cancer Center to commence the trial at its affiliate, Massachusetts General Hospital, or MGH. In parallel, we are conducting studies with TTX-MC138 in support of our planned investigational new drug, or IND, application for a Phase I/II clinical trial with TTX-MC138.

Our other preclinical programs include two solid tumor programs, TTX-siPDL1, an siRNA-based modulator of programmed death-ligand 1. TransCode also has three cancer-agnostic programs, TTX-RIGA, an RNA-based agonist of the retinoic acid-inducible gene I, or RIG-I, targeting activation of innate immunity 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 that activate cytotoxic immune responses against tumor cells.

All our therapeutic candidates are designed to utilize our proprietary delivery mechanism with the goal of significantly improving outcomes for cancer patients.

Targeted Therapeutic Delivery Background

For decades, ribonucleic acid, or RNA, has been a topic of investigation by the scientific community as a potentially attractive therapeutic modality because it can target any gene and it lends itself to rational and straightforward drug design. RNA-based therapeutics are highly selective to their targets, potentially applicable to a broad array of previously undruggable targets in the human genome. We believe that one of the major challenges to widespread use of RNA therapeutics in oncology and other indications has been the inability to deliver these molecules inside cells other than the liver.

Additionally, delivery remains a significant challenge with CRISPR-based genome editing tools as well as mRNAs in the context of cancer. We believe that our proprietary TTX delivery platform has the potential to resolve these key challenges. We believe overcoming the challenges of delivery would represent an important step in unlocking therapeutic access to a variety of documented targets involved in a range of cancers and other diseases.

TransCode has created a design engine to customize the development of targeted therapeutics that is modular, both at the levels of the core nanoparticle and therapeutic loading. The size, charge, and surface chemistry of the core iron oxide nanoparticle is designed so that it can be tuned to optimize the particles for the intended target and therapeutic load. The therapeutic load is designed to consist of synthetic oligonucleotides and other molecular moieties that can be adapted to the specific approach being developed. The approach can range from RNA interference, or RNAi, including small interfering RNAs, antisense oligonucleotides, and non-coding RNA mimics to mRNA-based cancer vaccines, CRISPR-based gene repair and replacement platforms, and Pattern Recognition Receptors such as RIG-I. We believe the platform can further be used for developing targeted radiolabeled therapeutics and diagnostics and other custom products targeting known and novel biomarkers and other genetic elements as they are discovered and validated.

The TTX platform is designed to overcome extracellular and intracellular delivery issues of stability, efficiency, and immunogenicity faced by existing lipid and liposomal nanoparticle platforms while optimizing targeting of and accumulation in tumors and metastases. We believe the ability to deliver targeted therapeutics inside tumors and metastases will potentially allow us to target genes and other important biomarkers for cancer treatment that have until now remained undruggable using other delivery systems.

Delivery System

The therapeutic potential of RNA in oncology has remained an unrealized promise due in large part, we believe, to the difficulty in safely and effectively delivering oligonucleotides, i.e., synthetic RNA molecules, to tumors. TransCode believes it is now closer to solving this challenge by means of our TTX platform. Our TTX platform leverages an iron-oxide nanoparticle, or IONP, approved for clinical use as a cancer imaging agent and in treating iron deficiency anemia, as the physical carrier.

The TTX technology has gone through over 18 years of research and development, or R&D, and optimization, including 12 years at Harvard Medical School and the Massachusetts General Hospital, by our scientific co-founders prior to company formation. As an expansion of the original platform design, we recently submitted a U.S. provisional patent application entitled "*Nanoparticles Comprising Payloads and Their In Vivo Delivery*" as our next generation IONP delivery platform. We believe that this expanded use platform has the potential to broaden TTX's targeted therapeutic delivery to include both mRNA vaccines as well as CRISPR candidates to tumors and metastases. The increased delivery opportunity could allow us to participate in additional rapidly growing global marketplaces. According to a recent analysis by Emergen Research, the global CRISPR Technology Market is expected to reach $3.94 billion by 2027. The global mRNA therapeutics market size was estimated to reach $33.82 billion in 2023 and is projected to grow at a compound annual growth rate of 24.58% to reach $158.20 billion by 2030 according to an April 2023 360iResearch™ publication.

Our TTX nanocarrier is designed to be tunable to pre-designed specifications to deliver therapeutic oligonucleotides to RNA targets in tumors and metastases without compromising the integrity of the oligonucleotide. We believe TTX nanocarriers differentiate us from competitive delivery approaches, many of which rely on lipid particles or chemical structures, such as GalNAc. These competitive delivery approaches effectively target sites in the liver but not sites in tumors and metastases elsewhere. Our nanocarrier is derived from, and is chemically similar to, nanoparticles extensively used in imaging (Feridex, from Advanced Magnetics) or for treating iron deficiency anemia (Feraheme, also from Advanced Magnetics).

Our TTX delivery platform is specifically designed to minimize early kidney and liver clearance, translating into a long circulation half-life that allows for efficient accumulation in tumors and metastases. Nanoparticles similar in formulation to ours have an excellent clinical safety record of low toxicity and immunogenicity, and their built-in imaging capabilities due to their iron core which is magnetic and visible with magnetic resonance imaging, or MRI, have the additional benefit of enabling quantification of the particles' delivery to target organs. The nanoparticles are functionalized with amino groups to provide stable links to the therapeutic oligonucleotides of interest through disulfide bonds. The nanoparticles are coated with dextran, a glucose polymer, to protect the oligonucleotides from degradation and to provide overall stability to the particle.

The small hydrodynamic size and the charge of the resulting nanoparticles are designed to maximize distribution throughout the tumor microvasculature, extravasation into the interstitium of tumors and metastases, and uptake by tumors. The physicochemical properties of the nanoparticles are expected to further facilitate their rapid uptake by tumors by exploiting the high metabolic activity of cancer cells, a process analogous to the mechanism behind the systemic loading of metastatic cancer cells with fluorodeoxyglucose for diagnostic Positron Emission Tomography. We believe the combined result of a hydrodynamically-favored distribution and a metabolically-triggered uptake will result in the enhanced ability of TransCode's nanoparticles to access genetic targets inside tumors.

Exemplified by our June 2022 filing of U.S. provisional application 63/356,449, TransCode initiated research and development efforts designed to introduce radiotherapy into the delivery of RNA therapeutic payloads using TTX. Two of TransCode's programs, TTX-MC138 and TTX-RIGA, are being assessed for radionuclide integration in either a systemically or locally delivered manner for both the treatment and diagnosis of solid tumors.

Advancing new RNA therapies through a modular approach

The TransCode TTX platform is modular by design, both at the level of the core nanoparticle and at the therapeutic loading. The size, charge, and surface chemistry of the core nanoparticles are designed to be tuned to optimize them for the intended target and therapeutic load. Also, the therapeutic load is designed to be adapted to the specific approach being developed, ranging from RNAi which includes small interfering RNAs, or siRNAs, antisense oligonucleotides, non-coding RNA mimics to mRNA–based cancer vaccines, and Clustered Regularly Interspaced Palindromic Repeats, or CRISPR, –based gene repair and replacement platforms as well as Pattern Recognition Receptors such as RIG-I.

Additionally, we are interested in pursuing diagnostic approaches for RNA targets that might be relevant and important to informing treatment of patients using RNA therapeutics. Our 2018 license with MGH includes a patented microRNA screening assay with the potential to detect expression of microRNAs in patient blood. We intend to optimize this diagnostic test to detect miR-10b in cancer patients as our first commercial testing product. If approved, this test could be used as a screening assay to detect metastasis in a variety of tumor types. Also, we believe we may be able to use this test to evaluate miR-10b expression before, during and after treatment to best determine timing of therapeutic intervention.

In September 2021, research conducted by MGH was published in Cancer Nanotechnology, entitled “Radiolabeling and PET-MRI microdosing of the experimental cancer therapeutic, MN-anti-miR10b, demonstrates delivery to metastatic lesions in a murine model of metastatic breast cancer.” This paper reported on an MGH study using a radiolabeled derivative of TTX-MC138 (referred to in the paper as MN-anti-miR10b). In this study, TTX-MC138 was tagged with copper-64, or Cu-64. As a result, highly sensitive and specific quantitative determination of pharmacokinetics and biodistribution, as well as observation of delivery of the Cu-64 labeled TTX-MC138 to metastases, was made in laboratory tests using noninvasive positron emission tomography-magnetic resonance imaging, or PET-MRI. The key results of the study suggest that TTX-MC138, when injected intravenously, accumulates in metastatic lesions. These results suggest that our TTX platform delivers its therapeutic candidate as intended and supports clinical evaluation of TTX-MC138. In addition, the MGH investigation describes a microdosing PET-MRI approach to measure TTX-MC138 biodistribution in cancer patients and its delivery to clinical metastases. (Microdoses are minute, subpharmacologic doses of a test compound, not greater than 0.1 micrograms.) The capacity to carry out microdosing PET-MRI studies in patients under an exploratory IND, or eIND, application could be important because it has the potential to facilitate FDA authorization of additional human studies. This research, published by Dr. Zdravka Medarova, our Chief Technology Officer and scientific co-founder, and others describes what we believe is an effective approach to assessing delivery of TTX-MC138 in metastatic cancer patients. Since the PET-MRI technique is sensitive enough to determine the concentration of radiolabeled drug in the sub-picomolar range, microgram quantities of the radiolabeled drug are believed to be sufficient to perform such a study in humans. We believe this capability has significant advantages in the initial phases of drug development. Because the low mass of the radiolabeled drug does not induce reactions in humans, we believe the regulatory process will be less complex.

Dr. Medarova’s paper suggests that the radiolabeling does not impact tumor cell uptake or the ability of TTX-MC138 to engage its target. The paper also shows that the biodistribution of Cu-64 labeled TTX-MC138, when injected at a microdose, reflects its biodistribution at the level of a therapeutic dose. These key findings are expected to enable a microdosing study with TTX-MC138 in patients which we believe:

(i) allows precise quantitation of the amount of TTX-MC138 delivered to the metastatic lesions because of the higher sensitivity and quantitative accuracy of positron emission tomography;

(ii) permits measurement of the pharmacokinetics and biodistribution of TTX-MC138 not only in the metastatic lesions but in other tissues throughout the body. This knowledge can inform Phase I/II clinical trial designs by allowing us to determine drug uptake and clearance from vital organs;

(iii) enables measurement of pharmacokinetic endpoints potentially informing dosing for Phase II/III clinical trials. Specifically, because of the high sensitivity and quantitative nature of PET-MRI, it may be possible to derive a more precise calculation of drug concentration in the metastatic lesions over time and then correlate that information to the effective dose defined in our preclinical studies; and

(iv) further informs patient enrollment during Phase II/III trials by allowing patient inclusion in the trials based on which patients’ metastases demonstrated accumulation of TTX-MC138 in prior trials.

Because of the benefits we believe we can derive from a microdosing Phase 0 trial, and reflecting the studies described in Cancer Nanotechnology, we intend to pursue a microdosing Phase 0 trial for our First-in-Human clinical trial.

Success in the microdosing study could also validate delivery generally for our TTX pipeline which potentially opens-up additional relevant RNA targets that have been previously undruggable. Concurrent with the Phase 0 study, we expect to complete studies to support an IND for a Phase I clinical trial with TTX-MC138.

In the microdose Phase 0 study, we plan to enroll up to 12 patients with late-stage advanced solid tumors, infuse a single microdose of radiolabeled TTX-MC138, and use PET-MRI to measure TTX-MC138 delivery to metastatic lesions and other tissues in the body. We plan to conduct the clinical portion of the study at a major cancer center.

IND Enabling Studies in Support of Phase I Clinical Trial

As of July 2023, we had completed the experimental portion of non-clinical IND-enabling studies in support of our planned application to conduct a Phase 1 clinical trial. We are also on track to complete Chemistry, Manufacturing and Control work, drug synthesis, and fill-finish of drug product manufactured to meet good manufacturing practices, or GMP, requirements that we intend to use in our planned Phase 1 trial.

SBIR Award

In April 2021, we received a Fast-Track Small Business Innovation Research award, or SBIR Award, from the National Cancer Institute to provide up to $2,392,845 to fund a two-phased research partnership between us and Massachusetts General Hospital. The program commenced on April 15, 2021, and is expected to end in March 2024. We received SBIR Award funds of $308,861 in May 2021, $1,129,316 in the second year of the award and $870,597 in April 2023 for the third year of the Award. In the SBIR Award application, we proposed performing key translational experiments including IND-enabling and supporting imaging studies using MRI to assess delivery and target engagement of TTX-MC138 in metastatic lesions of breast cancer patients. The experiments are designed to achieve the following aims:

SBIR Phase I:

Aim 1. Optimize a method for measuring miR-10b expression in breast cancer clinical samples.

SBIR Phase II:

Aim 2. File an IND application for TTX-MC138.

Aim 3. Use imaging to determine the uptake of TTX-MC138 by radiologically-confirmed metastases in breast cancer patients.

We believe that we have achieved the first milestone which included development and validation of a method for the use of a test called qRT-PCR to measure miR-10b expression in patient blood and tissue samples. The qRT-PCR test is often considered the gold standard for quantifying circulating miRNAs with high sensitivity and specificity and with a wide analytical measurement range. This validated test was used to identify the level that would be considered a positive expression of miR-10b in samples from metastatic cancer patients. An expected criterion for patient inclusion in our Phase 0 First-in-Human study is to enroll only patients with a positive expression of miR-10b. We also believe that we achieved the study's second milestone as we filed an IND application with FDA to support a clinical trial with TTX-MC138. We received funding for the third year of the Award in April 2023.

In August 2023, we intend to submit a Phase IIB Competing Renewal Application to extend funding of our SBIR Award in support of commercialization of TTX-MC138. If awarded, the Phase IIB award is expected to provide up to $4.5 million of non-dilutive funding over two years beginning in the first half of 2024.

Financial Operations Overview

From inception in January 2016 through approximately mid-2021, we devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, securing intellectual property rights, conducting limited research and development activities, and preparing for manufacturing clinical-trial quantities of our lead product candidate. Following our IPO, we have expanded our R&D activities and our company operations. We do not have any products approved for sale and have not generated any revenue from product sales. We may never be able to develop or commercialize a marketable product. We have not yet completed any clinical trials, obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities. Through June 30, 2023, we had received gross proceeds of $40.8 million primarily from our IPO, other equity financings, our SBIR Award and from borrowings obtained between 2018 and 2020 under convertible promissory notes.

We have incurred significant operating losses since inception. Our net losses were $9.2 million and $17.6 million for the six months ended June 30, 2023, and the year ended December 31, 2022, respectively. At June 30, 2023, we had an accumulated deficit of $37.0 million. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates for which there is no assurance of occurrence. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- continue preclinical studies and initiate clinical trials for TTX-MC138 and other product candidates we may develop;
- advance the development of our product candidate pipeline;
- continue to develop and expand our proprietary TTX platform to identify additional product candidates;
- obtain new intellectual property and maintain, expand and protect our intellectual property portfolio;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any;
- hire additional clinical, scientific, commercial and administrative personnel to increase our overall knowledge base, scientific expertise, experience and capabilities;
- acquire or license additional product candidates;
- expand our infrastructure and facilities to accommodate increased activities and personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our further transition to operating as a public company.

Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our business strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through sales of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

At June 30, 2023, we had cash of $3.6 million. We believe that these amounts will be sufficient to fund our operating expenses and capital expenditure requirements into September 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point, we will need to raise additional capital which cannot be assured. If we are unable to raise additional capital in sufficient amounts or on terms we find acceptable, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. See “Liquidity and capital resources.”

Impact of the Novel Coronavirus (COVID-19) Pandemic

Since it was reported to have surfaced in December 2019, a novel strain of coronavirus, or COVID-19, has spread across the world and has been declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have intensified and governments around the world, including in the United States, Europe and Asia, have implemented severe travel restrictions, social distancing requirements, stay-at-home orders and have delayed the commencement of some non-COVID-19-related clinical trials, among other restrictions. As a result, the current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. economy and in financial markets. We believe that COVID-19 precautions and effects have affected and will continue to directly or indirectly affect the timeline for some of our preclinical studies and possibly our planned clinical trials. As a result of the outbreak, many companies have experienced disruptions in their operations and in markets served. To date, we have initiated some precautionary measures and we may take additional temporary precautionary measures intended to help ensure our employees' well-being and minimize business disruption. These measures include devising contingency plans and securing additional resources from third-party service providers. Certain of our third-party service providers have also experienced delays, shutdowns or other business disruptions. We are continuing to assess the impact of the COVID-19 pandemic on our current and future business operations, including our expenses, preclinical studies and planned clinical studies, and other development timelines, as well as on our industry and the healthcare system.

Components of our results of operations

Revenue

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval of any product candidate, or license agreements with third parties, we may generate revenue in the future from product sales or licensing agreements. However, there can be no assurance as to when, if ever, we will generate any such revenue.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts and the development of product candidates. We expense research and development costs as incurred, which include:

- expenses incurred in performing preclinical and clinical development;
- expenses incurred to conduct the necessary preclinical studies and clinical trials related to seeking regulatory approval to market our product candidates that successfully complete clinical trials;
- expenses incurred under agreements with contract research organizations, or CROs, conducting drug discovery work, preclinical studies, and clinical trials for us, and with contract manufacturing organizations, or CMOs, engaged to produce preclinical and clinical drug substance and drug product for our research and development activities;
- other costs related to acquiring and manufacturing materials in connection with our drug discovery efforts and our preclinical studies, materials for our clinical trials, including manufacturing validation batches, as well as costs related to investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- payments made under third-party licensing, acquisition and option agreements;
- personnel-related expenses, including salaries, benefits, travel and other related expenses, and share-based compensation expense for research and development personnel;

- costs related to compliance with regulatory requirements; and
- allocated facilities costs, including rent and utilities, and depreciation and other facilities or equipment expenses.

We recognize external development costs based on an evaluation of the progress toward completion of specific tasks using information provided to us by our employees, consultants and service providers. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are subsequently expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

We intend to track our research and development expenses on a program-by-program basis. Our direct external research and development expenses comprise primarily payments to outside consultants, CROs, CMOs, research laboratories, and suppliers in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct external research and development expenses also include fees incurred under license and option agreements. We do not intend generally to allocate costs of management personnel, certain costs associated with our discovery efforts, certain supplies used in the laboratory, and certain facilities costs, including depreciation or other indirect costs, to specific programs when these costs are incurred across multiple programs and where it may not be practical to track them by program. We use internal resources along with outside parties primarily to conduct our research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally are expected to have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years if we commence planned clinical trials for TTX-MC138, as well as conduct other preclinical and clinical development, including submitting regulatory filings. In addition, we expect our discovery research efforts and related personnel costs will increase and, as a result, we expect our research and development expenses, including costs associated with share-based compensation, will increase significantly over prior levels. Also, we may incur additional expenses related to milestone and royalty payments to third parties with whom we have entered or may enter into license, acquisition and option agreements to assess, use or acquire intellectual property rights or rights to future product candidates.

In September 2021, we signed a statement of work with a European CMO to manufacture TTX-MC138 in accordance with good manufacturing practices, or GMP. Separately, we engaged a contract research organization, or CRO, to assist us in designing and conducting IND-enabling studies including pharmacokinetic, or PK, studies. These studies are designed to examine multiple parameters with a range of analytical support in support of regulatory submissions using radiolabeled or non-radiolabeled test substances. Toxicokinetic assessments can be conducted in parallel or concurrent with ongoing toxicology programs and in compliance with good laboratory practice, or GLP, requirements. We have also engaged an analytical testing laboratory to provide testing and other services, as well as documentation and reporting that meet regulatory requirements.

On July 29, 2022, we signed a five-year strategic collaboration agreement with The University of Texas M. D. Anderson Cancer Center (“MD Anderson”). Under this alliance, the Company anticipates making certain expenditures with respect to Phase I and Phase II clinical trials which it expects will be conducted in part by MD Anderson as a primary investigator site. MD Anderson will also provide preclinical work under the alliance. The details of clinical and preclinical work are to be mutually agreed by the parties prior to commencing work. We have committed to fund up to $10 million over the term of the collaboration, with $500,000 of such amount originally payable within the first year. Subsequent payments were scheduled to be $2 million on the first anniversary of the effective date of the agreement and $2.5 million on each of the second, third and fourth anniversaries thereof. The Company is currently in negotiations with MD Anderson regarding committed upcoming payments as a result of changes in personnel at MD Anderson and in planned work. There is no assurance regarding the outcome of discussions with MD Anderson.

MD Anderson's website indicates that “Strategic alliances and commercialization agreements aim to provide space for innovative solutions to accelerate breakthrough discoveries in cancer research while developing deeper relationships with companies that share a similar vision. This can be done through joint development opportunities, collaborations, licensing or a combination of these

elements.” Through our alliance, scientists from TransCode and MD Anderson will collaborate on preclinical studies seeking to further validate TransCode's therapeutic and diagnostic candidates, and to expand the reach of TransCode's discovery engine. The results of these studies are expected to inform future clinical trials with these agents, including trials to be led at MD Anderson.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from or related to any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain due to the numerous risks and uncertainties associated with product development and commercialization, including:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development;
- the requirement to establish an appropriate safety and efficacy profile in IND-enabling studies;
- the timing and terms of regulatory approvals, if any, to conduct clinical trials;
- the number of sites and patients needed to complete clinical trials, the length of time required to enroll suitable patients and complete clinical trials, and the duration of patient follow-ups;
- the timing, receipt and terms of marketing approvals, if any, from applicable regulatory authorities including the FDA and regulators outside the U.S.;
- the extent of any post-marketing approval commitments that may be required by regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers to supply the quantities and quality of product we need;
- development and timely delivery of clinical-grade and commercial-grade drug formulations as required for use in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- competitive developments;
- the impact of any business interruptions on our operations, including the timing and enrollment of patients in our planned clinical trials, or on operations of our manufacturers, suppliers, or other vendors resulting from the COVID-19 pandemic or similar public health crisis or for any other reason; and
- maintaining an acceptable safety profile of our product candidates following approval, if any, of our product candidates.

Any changes in or adverse outcome of any of these variables or others with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of staffing costs comprising mainly salaries, benefits, and share-based compensation expense for personnel serving in executive, finance, and other business functions; insurance costs, especially directors

and officers liability insurance; professional fees for legal, patent, consulting, investor and public relations, accounting, tax and audit services; corporate and office expenses, including facilities costs; and information technology costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our R&D activities, prepare for potential commercial activities including possible partnerships for the development or marketing of approved product candidates, if any, and the increased requirements of a larger and publicly-traded company. We also anticipate that we will incur significantly increased accounting, audit, tax, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company. Additionally, if and when we believe regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other personnel-related expenses as we prepare for commercial operations, especially as it relates to the sales and marketing of that product candidate. There is a risk that we could incur the foregoing expenses but not receive the anticipated regulatory approval.

In September 2021, we engaged an independent executive compensation advisory firm to support the continued development of our compensation programs and governance model for officers, directors and employees. Our goal is to ensure that our culture, values, and strategic priorities are effectively represented in our compensation philosophy and strategy.

Other income (expense)

Interest expense

Interest expense previously consisted primarily of accrued interest on convertible promissory notes and other charges related to the notes. Since the notes converted into shares of common stock concurrent with our IPO, we no longer incur interest expense on these notes. Under our payment program for directors and officers liability insurance, we incur certain financing charges.

Interest income

Interest income consists primarily of income earned on our cash balances. Our interest income has not been significant due to low cash balances and, since the IPO, low interest rates earned on our cash balances.

Grant income

From time to time, we apply for grant funding from government programs and may, in the future, apply for grants from non-government sources as well. There is no assurance that any grants will be awarded to us or, if awarded, that we will receive all the funds expected from such award. Grant payments received in advance of us performing the work for which the grant was awarded are recorded as deferred grant income on our balance sheets. Grant income is recognized in our statements of operations as and when earned for performance of the specific R&D activities for which the grants are awarded. Grant income earned in excess of grant payments received is recorded as grant receivable on our balance sheets.

Results of operations

The following table summarizes our unaudited results of operations for the periods indicated:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2023	2022	Change	2023	2022	Change
	(in thousands)					
Operating Expenses						
Research and Development	$ 2,966	$ 2,620	$ 346	5,557	$ 4,502	$ 1,055
General and Administrative	2,165	2,087	78	4,475	3,683	792
Total Operating Expenses	5,131	4,707	424	10,032	8,185	1,847
Operating Loss	(5,130)	(4,707)	(423)	(10,032)	(8,185)	(1,847)
Other Income (expense)						
Grant Income	789	35	754	868	42	826
Interest Income	—	1	(1)	5	2	3
Total Other Income (expense)	789	36	753	873	44	829
Net income (loss)	$ (4,342)	$ (4,671)	$ 329	(9,159)	$ (8,141)	$ (1,018)

Comparison of the three and six months ended June 30, 2023 and 2022

Research and development expenses

Research and development, or R&D, expenses increased $346 thousand and $1,055 thousand for the three and six months ended June 30, 2023, respectively, compared to the same periods the prior year. The increases were primarily due to purchases of materials, and R&D consulting services, offset in part by reduced regulatory and purchased services costs.

General and administrative expenses

General and administrative expenses increased $78 thousand and $792 thousand for the three and six months ended June 30, 2023, respectively, compared to the same periods the prior year. The increases were primarily a result of increased compensation and related personnel costs, and legal, consulting, technology and facilities costs, offset in part by reduced accounting and audit expenses, compliance and licensing costs, and other costs of being a public company.

Grant Income

Grant income increased $754 thousand and $826 thousand in the three and six months ended June 30, 2023, respectively, compared to the same periods the prior year. Grant income was recognized under an NIH grant awarded in April 2021 to fund certain costs to advance our lead therapeutic candidate into clinical trials. Charges under the grant in the three months ended June 30, 2022, did not commence until June 1, 2022, because notice of the award was not issued until May 31, 2022.

Liquidity and capital resources

Sources of liquidity

Since inception, we have not generated any revenue from product sales or any other sources, and we have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if ever. We have funded our operations to date primarily with proceeds from borrowings under convertible promissory notes, with funds from our IPO and other equity financings, and our SBIR Award. Through June 30, 2023, we had received gross cash proceeds of approximately $40.8 million from these sources.

At June 30, 2023, we had cash of $3.6 million. In the June RDO, we received approximately $6.1 million in net proceeds from the sale of common stock and PFWs, together with accompanying Series A-1 and Series A-2 Warrants. See Notes 9 and 10 to our

unaudited financial statements included elsewhere in this Quarterly Report on Form 10-Q for further information regarding the June RDO.

Future requirements

We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we advance preclinical activities and pursue clinical trials of TTX-MC138. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, tax, investor relations and other expenses that we did not incur as a private company.

The timing and amount of our operating expenditures will depend largely on our ability to, among other things:

- advance clinical development of TTX-MC138;
- manufacture, or have manufactured on our behalf, our preclinical and clinical drug materials and develop processes for commercial manufacturing of any product candidates that may receive regulatory approval;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval and intend to commercialize on our own;
- establish collaborations to commercialize any product candidates for which we obtain marketing approval but do not intend to commercialize on our own;
- expand our operational, financial and management systems and hire additional personnel, including personnel to support our clinical development, quality control, scientific research, manufacturing and commercialization efforts, our general and administrative activities and our operations as a public company; and
- obtain or develop new intellectual property and maintain, expand and protect our intellectual property portfolio.

At June 30, 2023, we had cash of $3.6 million. We believe that these funds will be sufficient to fund our operating expense and capital expenditure requirements into September 2023. We have based this estimate on assumptions that may prove wrong, and we could utilize our available capital resources sooner than we expect. We do not believe that our existing cash will be sufficient to fund our planned operating and capital expenditures for at least the next 12 months from the date of our financial statements, included elsewhere in this Quarterly Report on Form 10-Q. Changed circumstances may also result in the depletion of our capital resources more rapidly than we currently anticipate. These circumstances raise substantial doubt about our ability to continue as a going concern. We anticipate that we will require additional capital for additional research, development, clinical trials, as we seek regulatory approval of our product candidates, company operations, and for licenses or acquisitions of other product candidates we may choose to pursue. If we receive regulatory approval for TTX-MC138 or other product candidates we may develop, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, all of which will vary depending on where and how we choose to commercialize approved product candidates.

Because of the numerous risks and uncertainties associated with research, development and commercialization of biologic product candidates, we are unable to estimate the exact amount and timing of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, outcome and costs of conducting preclinical development activities, clinical trials, and other research and development;
- the costs, timing and outcome of regulatory review of our product candidates;

- the costs, timing and requirements to manufacture our product candidates to supply our preclinical development efforts and our clinical trials;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade product and building inventory to support commercial launch;
- the ability to receive non-dilutive funding, including grants from governments, organizations and foundations;
- the revenue, if any, received from commercial sales of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining, expanding and enforcing our intellectual property rights and defending intellectual property-related claims;
- the terms of any industry collaborations we may be able to establish;
- the extent to which we acquire or license other product candidates and technologies; and
- the efficiency with which we operate our business.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. There is no assurance that funding from any of the foregoing sources or otherwise will be available on acceptable terms, if at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests in our common stock may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in fixed payment obligations.

If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue or earnings streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash flows

The following table summarizes our unaudited cash flows for the periods indicated:

	Six months ended June 30,	
	2023	2022
	(unaudited) (in thousands)	
Net cash used in operating activities	$ (8,905)	$ (7,321)
Net cash used in investing activities	(31)	(73)
Net cash provided by financing activities	7,540	6
Net decrease in cash	$ (1,396)	$ (7,388)

Comparison of the six months ended June 30, 2023 and 2022

Operating activities

During the six months ended June 30, 2023, we used cash of $8,905 thousand in operating activities compared to using $7,321 thousand in the six months ended June 30, 2022. The cash used in operating activities in the 2022 period primarily reflected our net loss of $9,159 thousand, a $1,167 thousand decrease in accounts payable and accrued expenses, and an increase in prepaid expenses and other current assets of $730 thousand, offset in part by increased non-cash charges of $334 thousand for share-based compensation expense of, $177 thousand in amortization of our right-of-use asset, and depreciation of $61 thousand.

Changes in accounts payable and accrued expenses were generally due to the amounts and timing of vendor invoicing and payments.

Investing activities

During the six months ended June 30, 2023, we used cash of $31 thousand in investing activities, primarily increased purchases of laboratory and computer equipment, compared to $73 thousand in such purchases in the 2022 period.

Financing activities

During the six months ended June 30, 2023, we obtained cash of $7,540 thousand from financing activities, all of which reflected equity financings.

During the six months ended June 30, 2022, we obtained $6 thousand in cash from financing activities, all of which reflected proceeds related to an exercise of stock options.

Contractual obligations and commitments

At June 30, 2023, we had future minimum lease payments under one non-cancelable operating lease commitment of $663.3 thousand. We enter into contracts in the normal course of business with CMOs, CROs and other third parties for the manufacture of our product candidates, to support clinical trials and preclinical research studies and testing, and for other purposes. These contracts are generally cancelable by us. Any payments due upon cancellation of these contracts generally consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation although some agreements provide for termination fees or payments for the balance of the term of the agreement.

Collaboration Obligations

Our obligations under collaboration agreements primarily arise from a strategic collaboration agreement we entered with The University of Texas M. D. Anderson Cancer Center (“MD Anderson”) on July 29, 2022. Under this alliance, we anticipate making certain expenditures with respect to Phase I and Phase II clinical trials which we expect will be conducted in part by MD Anderson as a primary investigator site. MD Anderson will also provide preclinical work under the alliance. The details of clinical and preclinical work are to be mutually agreed by the parties prior to commencing work. The Company has committed to fund up to $10 million over the term of the collaboration. Of this amount, the initial payment schedule called for $500,000 to be paid within the first year. Subsequent payments were to be $2 million on the first anniversary of the effective date of the agreement and $2.5 million on each of the second, third and fourth anniversaries thereof. The Company is currently in negotiations with MD Anderson regarding committed upcoming payments as a result of changes in personnel at MD Anderson and in planned work. There is no assurance regarding the outcome of discussions with MD Anderson. The term of the agreement is five years or until the studies are completed, whichever is later, unless earlier terminated by either party for a material breach of the collaboration agreement or by M.D. Anderson as provided in the collaboration agreement.

Critical accounting policies and significant judgments and estimates

We have based our management’s discussion and analysis of financial condition and results of operations on our financial statements. Our financial statements are prepared in accordance with United States GAAP. The preparation of our financial statements

and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses and the disclosure of contingent assets and liabilities at the date of the financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for our judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate estimates and assumptions on an ongoing basis. Our actual results may differ from amounts derived from these estimates or from amounts obtained under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022, and our unaudited financial statements appearing elsewhere in this Quarterly Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Research and development expenses

In preparing our financial statements, we are required to estimate our accrued research and development expenses.

We rely to a significant extent on third parties to conduct preclinical studies, provide materials, and to provide clinical trial services, including trial conduct, data management, statistical analysis and electronic compilation. At the end of each reporting period, we compare payments made to each service provider to the estimated progress towards completion of the related project. Factors that we consider in preparing these estimates include materials delivered or services provided, milestones achieved, the number of patients enrolled in studies, and other criteria related to the efforts of these vendors. These estimates are subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, we record net prepaid or accrued expenses related to these costs.

The estimating process involves reviewing open contracts and purchase orders, communicating with our relevant personnel to identify services that have been performed on our behalf or deliveries of materials made to us, and estimating the level of service performed and the associated cost incurred for those services when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. As of each balance sheet date, we make estimates of our accrued expenses based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including research laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical testing and clinical trials; and
- CMOs in connection with the production of drug substance and drug product formulations for use in preclinical testing and clinical trials.

The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Share-based compensation

We measure the expense of share-based awards granted to employees, directors and others based on the fair value of the underlying award on the date of the grant. We recognize the corresponding compensation expense of those awards over the requisite service period, generally the vesting period of the respective award. As of June 30, 2023, we had issued restricted stock and stock options, each with service-based vesting conditions, and recorded share-based compensation expense resulting from those awards as

vesting occurred. All shares of restricted stock have vested and there is no further compensation expense to be recorded in connection with restricted stock. We would apply the graded-vesting method to all share-based awards with performance-based vesting conditions or to awards with both service-based and performance-based vesting conditions.

For share-based awards to consultants and non-employees, we recognize compensation expense over the period during which services are rendered by such consultants and non-employees until completed.

Determination of the fair value of common stock

As prior to our initial public offering there was no public market for our common stock, the estimated fair value of our common stock was determined by our Board as of the date of each share-based award. Based on the fact that most of our activities from inception through mid-2018 related to organizing the company, including identifying management, directors and advisors, business planning, identifying potential product candidates, acquiring or developing intellectual property, conducting a limited amount of research and development, establishing arrangements with third parties to manufacture initial quantities of our product candidates and component materials, and seeking financing, and that our preclinical development had not advanced significantly, the Board determined that the fair value of our common stock had remained relatively constant at its par value during this period. In September 2018, the Board retained an independent third-party appraisal firm to provide an estimate of the fair value of our common stock. In November 2018, the appraisal firm estimated that, as of June 30, 2018, the fair value of a single share of our common stock was $1.40. In March 2020, the appraisal firm estimated that as of December 31, 2019, it was $1.60 per share and in December 2020, it was estimated to be $78.20 per share as of October 1, 2020.

The valuations were performed in accordance with the Standards of the National Association of Certified Valuators and Analysts and in consideration of guidance from valuation literature, relevant court decisions, Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 820, Internal Revenue Service Revenue Ruling, or RR, 59-60, RR 68-609, and 26 Code of Federal Regulations, or CFR, Part 2, Section 1.409A. Estimates and processes used by the independent appraiser in performing the valuation are highly complex and include both objective and subjective factors. Assumptions underlying these valuations included certain estimates provided by the company's management to the appraisal firm, which estimates involved inherent uncertainties and application of management's judgment. Had significantly different assumptions or estimates been used, the fair value of our common stock and our share-based compensation expense could have been materially different. Further, those factors may have changed between the date of the then most recent valuation and the date of the grant.

Factors considered by the appraiser in determining the fair value of our common stock as of each grant date, included:

- our stage of development and business strategy;
- the progress of our research and development programs, including the status and results of preclinical studies and plans for clinical trials for TTX-MC138;
- our capital structure, including, if outstanding at the time of a grant, our convertible promissory notes and the superior rights and preferences of the notes relative to our common stock;
- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;
- our financial position, including cash on hand, and our historical and forecasted performance and results of operations;
- the absence of an active public market for our common stock;
- the likelihood of achieving a liquidity event, such as an IPO or sale of our company in light of prevailing market conditions; and
- an analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

If there is an active public trading market for our common stock, we do not expect it to be necessary for our board to estimate the fair value of our common stock in connection with our accounting for share-based awards that we may grant, because the fair value of our common stock will be determined based on the quoted market price of our common stock. We may, despite any development of an active trading market for our common stock, and pending a sufficient history of the volatility of the price of our own common stock, calculate the volatility component of the valuation using volatility measures for a group of publicly-traded companies we deem comparable for this purpose.

Factors that May Affect Future Results

You should refer to Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2022, for a discussion of important factors that may affect our future results.

Off-balance sheet arrangements

During the periods presented, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may affect our financial position and results of operations is disclosed in Note 2 to our financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Internal control over financial reporting

In preparation of our financial statements to meet the requirements of our IPO, we determined that material weaknesses in our internal control over financial reporting existed prior to our IPO which remain unremediated. See "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, "We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business." In September 2022, we retained an independent consulting firm to assist us improve our control systems and procedures and have recently implemented new software systems designed to enhance our ability to process financial transaction information.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the JOBS Act. We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards by delaying adoption of these standards until they would apply to private companies. We have elected to use the extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date on which we (i) are no longer an emerging growth company and (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of effective dates applicable to public companies.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of our initial public offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We will continue to be a smaller reporting company until either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we

are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies.

Information Technology Risks

Our data and computer systems are subject to threats from malicious software codes and viruses, phishing, ransomware, business email compromise attacks, or other cyber-attacks. In July 2021, we were subject to what we believe was a phishing attack. Although we do not believe this incident had a material impact on our business or financial condition, the number and complexity of these threats continue to increase. See Part I, Item 1.A. - Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2022, "We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure." The Company has taken and continues to take steps to mitigate the risk of cyberattacks including enhancing its email screening, engaging with computer support firms to provide forensics and training services, among other services, and enhancing security protocols for vendor payments. The Company intends to take additional steps to continue to enhance its cybersecurity defenses. Despite steps the Company has taken or may take in the future, there is no assurance that it will not suffer material and adverse consequences as a result of cyberattacks or other computer-based activities. In addition, there is no assurance that any steps we may take will be effective or prevent material adverse effects on our financial condition or results of operations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest rate risk

We are exposed to market risk related to changes in interest rates. At June 30, 2023 and 2022, our cash was held in checking and savings accounts at major U.S. banks. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, an immediate 10% change in the interest rate would not materially affect the fair market value of our investments or our financial position or results of operations.

At June 30, 2023, and December 31, 2022, we had no debt outstanding other than liabilities under our operating lease. As these liabilities are fixed, we do not believe we are subject to interest rate risk related to outstanding debt.

Foreign currency exchange risk

Our primary exposure to market risk is foreign exchange rate sensitivity to the Euro, the currency for certain of our major purchases. For the six months ended June 30, 2023 and 2022, we did not recognize foreign currency transaction losses. Foreign currency transaction losses, if any, are recorded as a component of other income (expense) in our statements of operations. An immediate 5% change in the Euro exchange rate would not have a material effect on our results of operations.

As we continue to develop our business, our results of operations and cash flows will likely be more affected by fluctuations in foreign currency exchange rates, including the Euro and other currencies, which could adversely affect our results of operations. To date, we have not entered into any foreign currency hedging contracts to mitigate our exposure to foreign currency exchange risk.

ITEM 4. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2023. Based upon such evaluation, and due to the material weakness described elsewhere in Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were not effective. In September 2022, we retained an independent consulting firm to assist us improve our control systems and procedures and have recently implemented new software systems designed to enhance our ability to process financial transaction information.

Management's Annual Report on Internal Control Over Financial Reporting

This Quarterly Report on Form 10-Q does not include a report of management's assessment regarding our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting:

There were no material changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the six months ended June 30, 2023, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any legal proceedings, and we are not aware of any pending or threatened legal proceedings against us that we believe could have a material adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors

Factors that could cause our actual results to differ materially from those in this Quarterly Report are any of the risks described in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC, and the risk factors set forth below. Any of these factors could result in a significant or material adverse effect on our business, results of operations or financial condition. Additional risk factors not currently known to us or that we currently deem immaterial may also have a material adverse effect on our business, financial condition or results of operations. You should review the risk factors in our Annual Report on Form 10-K and below for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in this Quarterly Report. We may disclose changes to such factors or disclose additional factors from time to time in our future filings with the SEC.

Current economic circumstances may harm our business, financial condition and results of operations.

Our overall performance depends, in part, on worldwide economic conditions. In recent months, we have observed increased economic uncertainty in the United States and abroad. Impacts of such economic circumstances include:

- reduced credit availability;
- higher borrowing costs;
- reduced liquidity;
- volatility in credit, equity and foreign exchange markets; and
- declines in equity valuations, especially in the biopharmaceutical sector; and bankruptcies.

These developments could lead to supply chain disruption, inflation, higher interest rates, and uncertainty about business continuity, which may adversely affect our business, financial condition and our results of operations. They are likely to make obtaining equity capital more difficult and more expensive, if available at all for which there is no assurance.

Rising inflation rates have increased our operating costs and could negatively impact our operations.

Inflation rates, particularly in the United States, have increased recently to levels not seen in decades. Increased inflation has resulted in increased operating costs (including our labor costs), and may result in reduced liquidity, and limitations on our ability to access capital, including by raising debt and equity capital. In addition, the United States Federal Reserve has raised, and is expected to further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks.

We could lose our listing on the Nasdaq Capital Market if we do not increase our stockholders' equity. The loss of our Nasdaq listing would in all likelihood make our common stock significantly less liquid and adversely affect its value.

As initially disclosed on our Current Report on Form 8-K filed with the SEC on May 18, 2023, we received a letter from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") on May 16, 2023, that we are not in compliance with the stockholders' equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) requires that companies listed on the Nasdaq Capital Market maintain stockholders' equity of at least $2,500,000 (the "Stockholders' Equity Requirement"). We were given 45 calendar days, or until June 30, 2023, to submit a plan to Nasdaq describing how we intend to seek to regain compliance with the Stockholders' Equity Requirement (the "Compliance Plan").

If the Compliance Plan was determined to be acceptable to the Staff, the Staff would have the discretion to grant the Company an extension of 180 calendar days from the date of the Staff notification to regain compliance with the Stockholders' Equity Requirement. The Company submitted the Compliance Plan to Nasdaq on June 30, 2023, and supplemented it with additional materials on July 24, 2023.

On July 26, 2023, the Company received a Delisting Determination Letter from the Staff advising the Company that the Staff had determined not to accept the Company's Compliance Plan, that the Company's request for an extension had been denied, and that the Company's common stock was subject to delisting from the Nasdaq Capital Market (the "Delisting Determination"). In accordance with Nasdaq Listing Rule 5815(a)(2), the Company was provided with seven calendar days, or until August 2, 2023, to request a hearing before the Nasdaq Hearings Panel (the "Panel") to appeal the Delisting Determination. The Company submitted a request for a hearing to Nasdaq, and on August 2, 2023, was notified by Nasdaq that an oral hearing (the "Hearing") by the Panel to discuss the Delisting Determination has been scheduled for October 2023. Accordingly, any delisting action by the Staff will be stayed at least until the Hearing has been held and a final written decision by the Panel has been issued, and until any extension granted by the Panel following the Hearing expires.

At the Hearing, the Company intends to present its plan to regain compliance with the Stockholders' Equity Requirement. Following the Hearing, the Panel will issue a final written decision to the Company concerning the Delisting Determination. There can be no assurance that the Company's plan will be accepted by the Panel or that, if it is, the Company will be able to regain compliance with the Stockholders' Equity Requirement. Also, the timing of the Panel's final written decision is unknown and cannot be predicted with any certainty.

Upon a delisting from the Nasdaq Capital Market, our stock would likely be traded in the over-the-counter inter-dealer quotation system, more commonly known as the OTC. OTC transactions involve risks in addition to those associated with transactions in securities traded on the securities exchanges, such as the Nasdaq Capital Market, or, together, Exchange-listed stocks. Many OTC stocks trade less frequently and in smaller volumes than Exchange-listed stocks. Accordingly, our stock would be less liquid than it would be otherwise. Also, the prices of OTC stocks are often more volatile than Exchange-listed stocks. Additionally, institutional investors are usually prohibited from investing in OTC stocks, and it might be more challenging to raise capital when needed.

We have identified conditions and events that raise substantial doubt about our ability to continue operations in the near-term. We may need to seek an in-court or out-of-court restructuring of our liabilities.

We may be forced to amend, delay, limit, reduce or terminate the scope of our development programs and/or limit or cease our operations if we are unable to obtain additional funding. As of June 30, 2023, we had cash and cash equivalents totaling $3.6 million. We do not believe that our cash as of June 30, 2023 will enable us to fund our operating expenses and capital requirements beyond September 2023. We will need to raise additional capital to continue as a going concern. The failure to obtain sufficient additional funds on commercially acceptable terms to fund our operations and satisfy our obligations to creditors may have a material adverse effect on our business, results of operations and financial condition and jeopardize our ability to continue operations in the near-term. We will likely need to consider additional cost reduction strategies, which may include, among others, amending, delaying, limiting, reducing, or terminating our development programs, and we may need to seek an in-court or out-of-court restructuring of our liabilities. In the event of such future restructuring activities, holders of our common stock and other securities will likely suffer a total loss of their investment.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Unregistered Sales of Equity Securities

None.

(b) Use of Proceeds from Initial Public Offering of Common Stock

None.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

ITEM 6. EXHIBITS

1.1*	Certificate of Amendment to Amended and Restated Certificate of Incorporation of TransCode Therapeutics, Inc.
4.1	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on June 6, 2023 (File No. 333-272082))
4.2	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.3 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on June 5, 2023 (File No. 333-272082))
4.3	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.4 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on June 5, 2023 (File No. 333-272082))
10.1	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 8-K, filed on June 6, 2023 (File No. 001-40363))
31.1*	Certification of principal executive officer pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended
31.2*	Certification of principal financial officer pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended
32.1**	Certification of principal executive officer pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code
32.2**	Certification of principal financial officer pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** This certification is being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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, thereunto duly authorized.

TRANSCODE THERAPEUTICS, INC.

Date: August 14, 2023

/s/ R. Michael Dudley
R. Michael Dudley
Chief Executive Officer

Date: August 14, 2023

/s/ Thomas A. Fitzgerald
Thomas A. Fitzgerald
Chief Financial Officer
(Principal Financial and Accounting Officer)

State of Delaware
Secretary of State
Division of Corporations
Delivered 08:14 AM 05/19/2023
FILED 08:14 AM 05/19/2023
SR 20232185542 – File Number 5933548

CERTIFICATE OF AMENDMENT TO THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF TRANSCODE THERAPEUTICS, INC.

TransCode Therapeutics, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "DGCL"), does hereby certify:

1. Pursuant to Section 242 of the DGCL, this Certificate of Amendment to the Amended and Restated Certificate of Incorporation (this "Certificate of Amendment") amends the provisions of the Amended and Restated Certificate of Incorporation of the Corporation, as amended (the "Charter").

2. This Certificate of Amendment has been approved and duly adopted by the Corporation's Board of Directors and stockholders in accordance with the provisions of Section 242 of the DGCL.

3. Upon this Certificate of Amendment becoming effective, the Charter is hereby amended as follows:

ARTICLE IV of the Charter is hereby amended by adding the following new paragraph at the end of such article:

"C. REVERSE STOCK SPLIT

Effective at 4:05 p.m., Eastern Time, on May 22, 2023 (the "**2023 Split Effective Time**"), every twenty (20) shares of common stock issued and outstanding or held by the Corporation as treasury shares as of the 2023 Split Effective Time shall automatically, and without action on the part of the stockholders, be combined, reclassified and changed into one (1) validly issued, fully paid and non-assessable share of common stock, without effecting a change to the par value per share of common stock, subject to the treatment of fractional interests as described below (the "**2023 Reverse Split**"). Notwithstanding the immediately preceding sentence, no fractional shares will be issued in connection with the combination effected by the preceding sentence. Stockholders of record who otherwise would be entitled to receive fractional shares in connection with such combination will instead be entitled to receive, in lieu of such fractional shares, an amount in cash equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing price of our common stock on The Nasdaq Capital Market on the date on which the 2023 Split Effective Time occurs. As of the 2023 Split Effective Time and thereafter, a certificate(s) representing shares of common stock prior to the 2023 Reverse Split is deemed to represent the number of post-2023 Reverse Split shares into which the pre-2023 Reverse Split shares were reclassified and combined. The 2023 Reverse Split shall also apply to any outstanding securities or rights convertible into, or exchangeable or exercisable for, common stock of the Corporation and all references to such common stock in agreements, arrangements, documents and plans relating thereto or any option or right to purchase or acquire shares of common stock shall be deemed to be references to the common stock or options or rights to purchase or acquire shares of common stock, as the case may be, after giving effect to the 2023 Reverse Split."

4. This Certificate of Amendment shall become effective at 4:05 p.m., Eastern Time, on May 22, 2023.

IN WITNESS WHEREOF, the undersigned authorized officer of the Corporation has executed this Certificate of Amendment to the Amended and Restated Certificate of Incorporation as of May 19, 2023.

TRANSCODE THERAPEUTICS, INC.

By: /s/ R. Michael Dudley
Name: R. Michael Dudley
Title: Chief Executive Officer

* _ * _ * _ *

EXHIBIT 31.1

CERTIFICATION PURSUANT TO SECURITIES AND EXCHANGE ACT OF 1934
RULE 13A-14 AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002
CERTIFICATION

I, Robert Michael Dudley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TransCode Therapeutics, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 14, 2023

By: /s/ Robert Michael Dudley
Robert Michael Dudley
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO SECURITIES AND EXCHANGE ACT OF 1934
RULE 13A-14 AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002
CERTIFICATION

I, Thomas A. Fitzgerald, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TransCode Therapeutics, Inc..

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 14, 2023

By: /s/ Thomas A. Fitzgerald
Thomas A. Fitzgerald
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY
ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of TransCode Therapeutics, Inc. (the "Company") for the period ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Michael Dudley, in my capacity as Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2023

By: /s/ Robert Michael Dudley
Robert Michael Dudley
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY
ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of TransCode Therapeutics, Inc. (the "Company") for the period ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas A. Fitzgerald, in my capacity as Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2023

By: /s/ Thomas A. Fitzgerald
Thomas A. Fitzgerald
Chief Financial Officer
(Principal Financial and Accounting Officer)