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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 September 30, 2022

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 November 4, 2022, the registrant had 12,977,234 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 need for additional financing;
- the design, conduct and outcome of our planned preclinical activities to support an eIND for our planned Phase 0 trial of a radiolabeled version of TTX-MC138, our lead therapeutic candidate focused on metastatic cancer treatment, and our ability to initiate and complete this trial;
- our ability to expand our therapeutic candidate portfolio through internal research and development or the acquisition or in-licensing of intellectual property assets;
- the impact of the COVID-19 coronavirus pandemic, including the spread of new strains of the virus, on our activities, including but not limited to our ability to enroll a sufficient number of patients to advance the above-described clinical trials;
- the results and timing of our preclinical and clinical trial activities;
- the therapeutic benefits, effectiveness and safety of our therapeutic candidates;
- our ability to receive regulatory approval for our therapeutic candidates in the United States, Europe and other geographies;
- the expected regulatory approval pathway for our therapeutic candidates, 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;
- 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;
- potential changes in regulatory requirements, and delays or negative outcomes from the regulatory approval process;
- 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;

- 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;
- our ability to attract, retain and motivate key personnel;
- our ability to generate revenue and become profitable; 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 disclosure we make in our reports filed with the United States Securities and Exchange Commission, or SEC.

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 symbols 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.

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

TRANSCODE THERAPEUTICS, INC.

BALANCE SHEETS

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash	$ 8,790,540	$ 20,825,860
Grant receivable	487,879	—
Prepaid expenses and other current assets	2,291,466	1,906,315
Total current assets	11,569,885	22,732,175
Property and equipment, net of depreciation	209,871	206,268
Deferred offering costs	235,817	—
Total assets	$ 12,015,573	$ 22,938,443
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,747,838	$ 2,503,569
Deferred grant income	23,538	30,528
Total current liabilities	3,771,376	2,534,097
Total liabilities	3,771,376	2,534,097
Stockholders' equity:		
Preferred stock – $0.0001 par value; 10,000,000 and 5,000,000 shares authorized at September 30, 2022, and December 31, 2021, respectively; - 0- shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock – $0.0001 par value, 290,000,000 shares authorized at September 30, 2022, and December 31, 2021; 12,977,234 and 12,904,574 shares issued and outstanding at September 30, 2022, and December 31, 2021, respectively	1,298	1,291
Additional paid-in capital	30,979,092	30,708,336
Accumulated deficit	(22,736,193)	(10,305,281)
Total stockholders' equity	8,244,197	20,404,346
Total liabilities and stockholders' equity	$ 12,015,573	$ 22,938,443

See accompanying notes to financial statements.

TRANSCODE THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 3,044,024	$ 992,946	$ 7,545,628	$ 1,468,457
General and administrative	1,909,536	1,366,963	5,592,727	1,696,444
Total operating expenses	4,953,560	2,359,909	13,138,355	3,164,901
Operating loss	(4,953,560)	(2,359,909)	(13,138,355)	(3,164,901)
Other income (expense)				
Change in fair value of derivative liabilities	—	—	—	(867,000)
Change in fair value of warrant liability	—	(1,340)	—	(6,109)
Grant income	654,949	31,735	696,669	88,786
Interest expense	—	(333)	—	(95,070)
Interest income	9,001	141	10,774	154
Total other income (expense)	663,950	30,203	707,443	(879,239)
Net loss	$ (4,289,610)	$ (2,329,706)	$ (12,430,912)	$ (4,044,140)
Basic and diluted loss per share				
Net loss	$ (4,289,610)	$ (2,329,706)	$ (12,430,912)	$ (4,044,140)
Weighted-average common shares outstanding	12,977,234	11,526,514	12,977,234	6,932,982
Net loss per share	$ (0.33)	$ (0.20)	$ (0.96)	$ (0.58)

See accompanying notes to financial statements.

TRANSCODE THERAPEUTICS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)

	Common Stock		Additional Paid-In	Subscription	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Receivable	Deficit	(Deficit)
Three and nine months ended September 30, 2022						
Balance, December 31, 2021	12,904,574	$ 1,291	$ 30,708,336	$ —	$ (10,305,281)	$ 20,404,346
Net loss	—	—	—	—	(3,470,070)	(3,470,070)
Exercise of stock options	72,660	7	5,982	—	—	5,989
Share based compensation	—	—	60,573	—	—	60,573
Balance, March 31, 2022	12,977,234	1,298	30,774,891	—	(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	12,977,234	1,298	30,873,490	—	(18,446,583)	12,428,205
Net loss	—	—	—	—	(4,289,610)	(4,289,610)
Share based compensation	—	—	105,602	—	—	105,602
Balance, September 30, 2022	12,977,234	$ 1,298	$ 30,979,092	$ —	$ (22,736,193)	$ 8,244,197
Three and nine months ended September 30, 2021						
Balance, December 31, 2020	4,636,216	$ 464	$ 65,949	$ (12,763)	$ (3,461,882)	$ (3,408,232)
Net loss	—	—	—	—	(4,485,338)	(4,485,338)
Interest on subscription receivable	—	—	128	(128)	—	—
Share based compensation	—	—	48,431	—	—	48,431
Balance, March 31, 2021	4,636,216	464	114,508	(12,891)	(7,947,220)	(7,845,139)
Net income	—	—	—	—	2,770,904	2,770,904
Interest on subscription receivable	—	—	103	(103)	—	—
Proceeds from subscription receivable	—	—	—	3,640	—	3,640
Share based compensation	—	—	34,514	—	—	34,514
Balance, June 30, 2021	4,636,216	464	149,125	(9,354)	(5,176,316)	(5,036,081)
Net loss	—	—	—	—	(2,329,706)	(2,329,706)
Issuance of common stock in initial public offering, net of offering costs	7,187,500	719	25,399,954	—	—	25,400,673
Conversion of convertible promissory notes, including embedded derivative, to common stock upon completion of initial public offering	1,068,135	107	4,991,324	—	—	4,991,431
Exercise of warrants	12,723	1	64,751	—	—	64,752
Interest on subscription receivable	—	—	92	(92)	—	—
Share based compensation	—	—	64,051	—	—	64,051
Balance, September 30, 2021	12,904,574	$ 1,291	$ 30,669,297	$ (9,446)	$ (7,506,022)	$ 23,155,120

See accompanying notes to financial statements.

TRANSCODE THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (12,430,912)	$ (4,044,140)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	69,101	13,482
Share-based compensation expense	264,774	146,996
Change in fair market value of derivative liabilities	—	867,000
Non-cash interest expense	—	39,471
Change in fair market value of warrant liability	—	6,109
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(385,152)	(2,701,186)
Accounts payable and accrued expenses	1,234,270	1,766,148
Deferred grant income	(6,990)	220,075
Grants receivable	(487,879)	—
Payment of amount due to related parties	—	(35,685)
Accrued interest on convertible promissory notes	—	55,598
Net cash used in operating activities	(11,742,788)	(3,666,132)
Cash flows from investing activities:		
Purchase of equipment	(72,704)	(169,092)
Net cash used in investing activities	(72,704)	(169,092)
Cash flows from financing activities:		
Proceeds from initial public offering (IPO) of common stock, net of offering costs	—	26,335,100
Proceeds from exercise of stock options	5,989	—
Proceeds from subscription receivable	—	3,640
Proceeds from exercise of warrants	—	29,267
Payments of deferred offering costs	(225,817)	(860,943)
Net cash provided by (used in) financing activities	(219,828)	25,507,064
Net change in cash	(12,035,320)	21,671,840
Cash, beginning of period	20,825,860	828,016
Cash, end of period	$ 8,790,540	$ 22,499,856
Supplemental disclosure of cash flow		
Cash paid during the year for:		
Interest	$ 20,623	$ —
Supplemental disclosure of non-cash investing and financing activities:		
Accrued interest on subscriptions receivable	$ —	$ 323
Debt discounts associated with derivative liabilities of convertible promissory notes	$ —	$ 37,471
Conversion of convertible promissory notes, including embedded derivative, to common stock	$ —	$ 4,991,431
Deferred offering costs included in accounts payable and accrued expenses	$ 10,000	$ —
Deferred offering costs adjusted into additional paid-in capital in connection with IPO	$ —	$ 73,484
Fair value of warrant liability associated with warrant exercise	$ —	$ 35,485
Underwriting discounts and commissions paid from gross proceeds of IPO	$ —	$ 2,414,900

See accompanying notes to financial statements.

TransCode Therapeutics, Inc.
Notes to Financial Statements
(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 cancer. TransCode is preparing for its first clinical trial. The Company's lead therapeutic candidate, TTX-MC138, comprises 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 7,187,500 shares of common stock in connection with the IPO, including exercise of the underwriter's over-allotment option, at an initial offering price of $4.00 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 312,500 shares of Company common stock at an exercise price of $5.00 per share (125% of the initial public offering price). Upon the closing of the IPO, outstanding convertible promissory notes converted into 1,068,135 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 nine months ended September 30, 2022, net cash used in operating activities was approximately $11.7 million and the Company's net loss was approximately $12.4 million. As of September 30, 2022, the Company had an accumulated deficit of approximately $22.7 million and approximately $8.8 million in cash.

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

The Company plans to expand development of its lead therapeutic candidate and other candidates, and explore strategic partnerships. Management believes that current cash along with the approximately $928 thousand it expects to receive under year-two of the Company's SBIR Award (see Note 7) are sufficient to fund operations and capital requirements through the first quarter of 2023, but does not believe that existing cash will 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 September 30, 2022, the Company's primary source of capital was from the sale of equity securities in the IPO, previous sales of convertible promissory notes and funds received under the SBIR Award. 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 from funds expected under the SBIR Award.

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

The interim financial statements included herein are unaudited. 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 statements include all adjustments, consisting only of normal, recurring adjustments, necessary for a fair presentation of the financial position of TransCode Therapeutics, Inc. at September 30, 2022, its results of operations for the three and nine months ended September 30, 2022 and 2021, and its cash flows for the nine months ended September 30, 2022 and 2021. 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, 2021, 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. 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.

Significant items subject to such estimates and assumptions include but are not limited to the valuation of share-based compensation, income from grants, derivative liabilities, and warrant liability. 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.

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

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

Basic net earnings (loss) per share is determined by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net earnings (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 earnings (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. At times, the Company's cash balances in U.S. banks may exceed the levels of insured amounts under the Federal Deposit Insurance Corporation (FDIC).

(e) Fair Value of Financial Instruments

The Company's financial instruments at September 30, 2022, and December 31, 2021, included cash, accounts payable, and accrued expenses. Cash is reported at fair value. The recorded carrying amount of accounts payable and accrued expenses approximate their fair value due to their short-term nature.

(f) Research and Development

Research and development costs generally 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
(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 stock-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.

(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

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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) Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash. The Company generally maintains balances in various accounts at one or more U.S. banks in amounts that may exceed federally insured limits. The Company has not experienced any losses related to its cash and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking balances.

(l) 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.

(m) Recent Accounting Pronouncements

In November 2021, the FASB, issued Accounting Standards Update No. 2021-10 entitled "Government Assistance (Topic 832), Disclosures by Business Entities about Government Assistance". This ASU requires enhanced disclosures related to the Company's contracts with the U.S. Government that are accounted for by applying a grant or contribution accounting model by analogy. The new disclosure requirements include information about the nature of the transactions and the related accounting policy used to account for the transactions; the line items on the balance sheet and income statement that are affected by the transactions, and the amounts applicable to each financial statement line item; and significant terms and conditions of the transactions, including commitments and contingencies. The ASU is effective for annual periods beginning after December 15, 2021. The Company's adoption of this standard on January 1, 2022, did not have a significant effect on its financial statements.

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(n) Reverse Stock Split

On March 22, 2021, the Board and shareholders of the Company approved a reverse split of the Company's common stock at a ratio of one share for every 1.6486484 shares previously held. 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.

(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 and accounts payable and accrued liabilities approximated fair value as they are short term in nature.

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	September 30, 2022	December 31, 2021
Prepaid operating expenses	$ 172,652	$ 61,459
Contract manufacturers and research organizations	295,023	441,593
Insurance premiums	1,814,381	1,393,853
Deposits	9,410	9,410
	$ 2,291,466	$ 1,906,315

(5) Property and Equipment

Property and equipment, net consisted of the following:

	September 30, 2022	December 31, 2021
Laboratory and computer equipment	$ 320,226	$ 247,522
Less accumulated depreciation	(110,355)	(41,254)
Total property and equipment, net	$ 209,871	$ 206,268

Depreciation expense for the nine months ended September 30, 2022 and 2021, was $69,101 and $13,482, respectively.

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(6) Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	September 30, 2022	December 31, 2021
Professional and general consulting fees	$ 299,378	$ 218,476
R&D-related – CMOs, CROs, supplies, equipment and consulting	1,687,011	595,465
General expenses	167,357	256,463
Insurance premiums	1,438,901	945,928
Payroll and benefits	134,704	482,237
Accrued license payments	20,487	5,000
	$ 3,747,838	$ 2,503,569

At September 30, 2022, and December 31, 2021, the Company's outstanding payables to CROs or CMOs included above were $1,334,632 and $386,057, 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, or SBIR, Award from the National Cancer Institute of the National Institutes of Health (the "NIH"). The Award is expected to provide 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 first-year funding of $308,861 which it recorded as deferred grant income. In May 2022, second-year funding of $1,129,316 was made available to the Company. Income under the grant's first year funding was recognized as work under the grant was completed. In the second year of the grant, the Company will draw available funds in arrears. The Company recognized grant income of $654,949 and $696,669, respectively, for the three and nine months ended September 30, 2022, and $31,735 and $88,786 for the three and nine months ended September 30, 2021, respectively. The Company recorded grant income receivable of $487,879 at September 30, 2022, and $0 at December 31, 2021. The Company had deferred grant income of $23,538 and $30,528 at September 30, 2022, and December 31, 2021, 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 has subleased approximately 2,484 square feet of laboratory space with room for minor administrative functions. The Company may also use shared laboratory equipment at the facility. The monthly rental is $6,521 and the Company pays an additional amount for its allocated share of operating expenses, currently $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 extends through December 31, 2022, includes an option to extend the sublease upon the mutual agreement of the parties, and is cancelable anytime upon 90 days' notice. Based on the foregoing, the Company's total sublease commitment from October 1, 2022, through December 31, 2022, is $30,828. The Company and MBI intend to extend the sublease after December 31, 2022, on a month-to-month basis.

(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

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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 September 30, 2022, and December 31, 2021, 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.

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.

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Option Agreement – LIN28B

The Company signed an Exclusive Option And Internal Evaluation License Agreement (the "Option") with the Licensor effective February 15, 2021. Under the Option, the Company has (1) the exclusive right to negotiate a license of a certain technology patented by the Licensor and (2) a non-exclusive internal evaluation license to allow the Company to evaluate the technology. The Option provided for a six-month term at a cost of $5,000 with a right to extend, upon the mutual agreement of the parties, for an additional six months for a second $5,000 payment. In August 2021, the Licensor agreed to extend the initial term of the Option until November 15, 2021, at no cost to the Company. Effective November 8, 2021, the Company and the Licensor agreed to extend the Option through May 22, 2022, at a cost to the Company of $5,000. Effective September 28, 2022, the Company and the Licensor agreed to further extend the Option through June 30, 2023, at a cost to the Company of $10,000. The Company is also responsible for patent costs related to the subject technology incurred by Licensor during the Option period. Patent costs incurred by the Licensor prior to the effective date will not be reimbursed under the Option.

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 September 30, 2022, and December 31, 2021, the Company had accrued $20,487 and $5,000, respectively, in license payments under the foregoing arrangements included in accounts payable and accrued expenses. All amounts due at September 30, 2022, and December 31, 2021, have been paid.

(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 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. The Company has committed to fund up to $10 million over the term of the collaboration, with $500,000 payable within the first year. Subsequent payments are $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. Activities conducted under the arrangement with MD Anderson are research and development activities. Therefore, the Company records all costs incurred under the arrangement as research and development costs in its Statements of Operations. Total expenses incurred under the arrangement for the nine months ended September 30, 2022 and 2021, were $250,000 and $0, respectively.

(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.

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(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 September 30, 2022, and December 31, 2021, the Company did not have any pending legal actions.

(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 September 30, 2022, and December 31, 2021.

(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.

In July 2021, the Company was subject to what it believes was a sophisticated computer-based phishing attack involving $526,435 of which $45,682 was recovered in five days while the $480,753 balance was recovered on October 15, 2021. Management believes this incident had an immaterial impact on the Company's financial condition and continues to review its computer-related policies to implement additional defenses.

(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. 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 September 30, 2022, and December 31, 2021, the Company had 12,977,234 and 12,904,574 shares of common stock issued and outstanding, respectively. Of shares sold in 2018, an aggregate of 292,250 shares were issued to two purchasers in exchange for subscriptions receivable bearing interest at 4% per annum and secured by the underlying restricted shares. Both subscriptions receivable and accumulated interest were repaid in 2021. The preferred stock is undesignated; no shares of preferred stock have been issued.

The Company's IPO was completed on July 13, 2021, in which it sold 7,187,500 shares at a public offering price of $4.00 per share. The gross proceeds from the IPO were $28,750,000 from which the Company paid $2,415,000 of underwriting commissions and expenses and $934,427 of other offering expenses. The underwriter also paid $100 in aggregate for the underwriter warrants issued in connection with the IPO. See Note 10.

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(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 nine months ended September 30, 2022, 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 312,500 shares of Company common stock at an exercise price of $5.00 per share, which amount is 125% of the initial public offering price. The warrants have a five-year term and became exercisable on January 9, 2022. All of the warrants were outstanding at September 30, 2022, and December 31, 2021. The Company accounts for these warrants as a component of stockholders' equity.

(11) Share-Based Compensation

From inception through October 2018, the Company sold shares of restricted stock to co-founders, directors, managers, and advisors generally at prices believed to be fair market value at the time of the sale. Shares of restricted stock were reserved at the time of issue. To the extent that the sale price was less than the estimated fair market value at the grant date, a charge was recorded for the periods in which such shares vested. The vesting period for restricted stock was generally two to three years. All shares of restricted stock had vested by December 31, 2021.

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 3,032,787 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 2,500,000 shares of the Company's common stock. The number of options or other awards available under the 2021 Plan increased 645,228 shares in January 2022.

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.

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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 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 1,756,279 shares of common stock under the 2020 Plan. In 2021, the Board awarded options to purchase 36,393 shares of common stock under the 2020 Plan. Of the options issued under the 2020 Plan, options for 72,660 shares were exercised in January 2022 and options for 78,979 shares terminated in December 2021. In 2022, the Board awarded options to purchase 259,000 shares of common stock in February at an exercise price of $2.45 per share, 194,000 shares of common stock in March at an exercise price of $2.12 per share, and 28,500 shares in June at an exercise price of $1.24 per share under the 2021 Plan, all of which were outstanding at September 30, 2022. In September 2022, the Board approved an award of options to purchase 242,500 shares of common stock for which the date of grant was October 3, 2022, at an exercise price of $1.07 per share.

At September 30, 2022, there were 1,362,107 options outstanding that were vested and exercisable. All options vested at that date, had been awarded under the 2020 Plan; no options awarded under the 2021 Plan had vested. 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, 2020	1,756,279	$ 0.25	5.9
Granted	36,393	3.91	5.5
Exercised	—	—	—
Forfeited	78,979	—	—
Outstanding at December 31, 2021	1,713,693	0.33	5.2
Granted	481,500	2.27	9.6
Exercised	72,660	0.08	—
Forfeited	—	—	—
Outstanding at September 30, 2022	2,122,533	$ 0.77	5.8

The intrinsic value of the outstanding options as of September 30, 2022, was $700,436.

Option valuation

The assumptions that the Company used to determine the grant-date fair value of options granted in the nine months ended September 30, 2022 and 2021, were as follows:

	Nine months ended September 30,	
	2021	2022
Risk-free interest rate	0.59%	1.38% - 2.79%
Expected term (in years)	6.0	3.5 - 6.0
Expected volatility	97.2%	93.2%
Expected dividend yield	—	—
Fair value per share of underlying stock	$3.91	$1.24 - $2.45

The weighted average grant date fair value per share of the options granted was $1.81 for those granted in February 2022, $1.61 for those granted in March 2022, and $0.95 for those granted in June 2022.

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The Company recorded share-based compensation expense of $105,602 and $264,774 during the three months and nine months ended September 30, 2022, respectively, and $64,052 and $146,996 during the three months and nine months ended September 30, 2021, respectively. Share-based compensation in the three and nine months ended September 30, 2022, was entirely related to stock options. In the three months ended September 30, 2021, share-based compensation expense was entirely related to stock options while in the nine months ended September 30, 2021, it included $1,397 related to restricted stock. The remaining share-based compensation expense to be recognized in the future is $778,581 over approximately 2.1 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 150,000 shares of common stock. The number of shares of common stock available through the ESPP increased by 90,000 shares in January 2022 and may be increased each subsequent year by up to 90,000 shares.

(13) Net Loss Per Share

The Company reported net losses for the three months and nine months ended September 30, 2022 and 2021, respectively. 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. The effect of their inclusion would have been antidilutive.

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Basic loss per share				
Net loss	$ (4,289,610)	$ (2,329,706)	$ (12,430,912)	$ (4,044,140)
Weighted-average common shares outstanding	12,977,234	11,526,514	12,977,234	6,932,982
Net loss per share	$ (0.33)	$ (0.20)	$ (0.96)	$ (0.58)
Diluted loss per share				
Net loss	$ (4,289,610)	$ (2,329,706)	$ (12,430,912)	$ (4,044,140)
Weighted-average common shares outstanding	14,651,841	12,611,893	14,651,841	7,844,750
Net loss per share	$ (0.29)	$ (0.18)	$ (0.85)	$ (0.52)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Shares issuable on exercise of:				
Vested options	1,362,107	824,962	1,362,107	824,962
Underwriter warrants	312,500	260,417	312,500	86,806

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(14) Income Taxes

The Company's income tax benefit (expense) was $0 for the three and nine months ended September 30, 2022 and 2021. The Company has recorded a full valuation allowance against its net deferred tax assets as of September 30, 2022, and December 31, 2021, 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 nine months ended September 30, 2022 and 2021, was fully offset by changes in the valuation allowance.

As of September 30, 2022, and December 31, 2021, 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) Related-Party Transactions

Between inception and mid-2018, major shareholders and co-founders funded certain expenses of the Company. The aggregate amount of these expenses, $35,685, was reimbursed by the Company during 2021.

In April 2021, three members of the Company's management advanced an aggregate of $31,500 to the Company to enable it to pay certain Company IPO expenses. These advances were repaid in full, without interest, on May 13, 2021.

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, 2021, 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, 2021, 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, 2021, which are included in our Annual Report on Form 10-K for the year ended December 31, 2021.

Company Overview

TransCode Therapeutics is an RNA oncology company created on the belief that cancer can be more effectively treated through the intelligent design and effective delivery of RNA therapeutics. For decades, 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 making available a broad array of previously undruggable targets in the human genome. The therapeutic potential of RNA in oncology remains unrealized due in large part to the difficulty in safely and effectively delivering synthetic RNAs called oligonucleotides to tumors. TransCode believes it has solved this challenge. The company has developed an RNA delivery platform, the TTX platform, which leverages an iron oxide nanoparticle already approved as a clinical cancer imaging agent and treatment for iron deficiency anemia, as the physical carrier of the oligonucleotide.

Our TTX delivery system is built around a core iron oxide nanoparticle designed to minimize kidney and liver clearance. This is expected to translate into a long circulation half-life that allows for efficient accumulation of the therapeutic candidate in tumor cells and metastatic sites. Nanoparticles similar in design to those we use have an excellent clinical safety record of low toxicity and low immunogenicity. Further, the ability to image these particles enables quantification of their delivery to target tissues.

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 can be tuned to optimize them for the intended target and therapeutic load. Also, the therapeutic load can be adapted to the specific approach being developed, ranging from RNA interference, or 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 retinoic acid inducible gene, or RIG-I. The company believes that the TTX platform can further be used for developing RNA-targeted radiolabeled therapeutics and diagnostics candidates and other custom products targeting known and novel biomarkers and other genetic elements as they are discovered and validated. The TTX platform is intended to overcome issues of stability, efficiency, and immunogenicity faced by existing lipid and liposomal nanoparticle platforms while optimizing delivery to, and accumulation in, tumor cells and metastatic sites.

The company's 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, glioblastomas, and others. TransCode expects to submit an exploratory investigational new drug, or eIND, application to conduct a Phase 0 clinical trial using radiolabeled TTX-MC138 with the objective of demonstrating delivery to metastatic lesions in patients with advanced solid tumors. In parallel, the company is conducting IND-enabling studies for a Phase I/II clinical trial with TTX-MC138.

The company's other preclinical programs include two solid tumor programs: TTX-siPDL1, an siRNA-based modulator of programmed death-ligand 1, or PD-L1, and TTX-siLIN28B, an siRNA-based inhibitor of RNA-binding protein LIN28B. TransCode also has three cancer agnostic programs: TTX-RIGA, an RNA–based agonist of the RIG-I-driven immune response in the tumor microenvironment; TTX-CRISPR, a CRISPR/Cas9–based therapy platform for the repair or elimination of cancer-causing genes inside tumor cells; and TTX-mRNA, an mRNA-based platform for the development of cancer vaccines meant to activate cytotoxic immune responses against tumor cells.

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

We are also exploring LIN28B as a potential target in pancreatic cancer and other solid tumors under an option to license an siRNA technology from The General Hospital Corporation, d/b/a Massachusetts General Hospital, or MGH. The option allows us time to complete our evaluation of this technology. Should the results of the evaluation meet our criteria for including this technology in our portfolio, we intend to negotiate adding it to our existing MGH license.

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 blood samples from cancer patients with metastasis to compare our test results to standard of care measurements made using PCR, the gold standard of microRNA detection. Should we be able to determine that our test is able to detect microRNAs in blood samples with accuracy comparable to PCR results, we would expect to seek FDA approval of our assay. If approved, this test could be used as a screening assay to detect metastasis in a variety of tumor types. Also, 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 candidate in the sub-picomolar range, microgram quantities of the radiolabeled drug candidate 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 candidate 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 trial with TTX-MC138 in patients. We believe that a microdosing trial has numerous advantages:

(i) allows more 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. By contrast, imaging of drug delivery by MRI alone is much less sensitive and less quantitative;

(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 candidate uptake and clearance from vital organs. By contrast, measurement of TTX-MC138 delivery by MRI alone would only allow us to assess drug candidate accumulation in the metastatic lesions;

(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 precise calculation of drug candidate 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 trial 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 trial, we expect to continue studies to support an IND for a Phase I clinical trial with TTX-MC138.

In the microdose Phase 0 trial, we plan to enroll up to 12 patients with advanced metastatic 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 trial at a major cancer center.

Orphan Drug Designation

In June 2022, the U.S. Food and Drug Administration, or FDA, granted our request for orphan drug designation, or ODD, for TTX-siPDL1 for the treatment of pancreatic cancer. ODD status provides several potential benefits including seven years of marketing exclusivity if the designated candidate subsequently receives FDA marketing approval, tax credits for qualified R&D expenses, and an exemption from payment of the Prescription Drug User Fee Amendment (PDUFA) filing fee, a savings estimated to be more than $3 million.

SBIR Award

In April 2021, we received a Fast-Track Small Business Innovation Research award, or SBIR Award, from the National Cancer Institute. The SBIR Award is expected 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 and were notified in May 2022 that $1,129,316 of funding for the second year of the Award has been made available to the company. The company expects to receive up to $870,684 in the third year of the SBIR. If we achieve the milestones associated with a particular stage sooner than scheduled at the time of the SBIR Award, we may receive the funding for the subsequent stage sooner than originally scheduled. There is no guarantee that funds awarded for the third year of the SBIR grant will be received or not reduced in the sole discretion of the funding agency.

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.

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 September 30, 2022, we had received gross proceeds of approximately $31.5 million primarily from our IPO and from borrowings obtained between 2018 and 2020 under convertible promissory notes.

We have incurred significant operating losses since inception. Our net losses were approximately $12.4 million and approximately $6.8 million for the nine months ended September 30, 2022, and the year ended December 31, 2021, respectively. At September 30, 2022, we had an accumulated deficit of approximately $22.7 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 or technologies;
- 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 September 30, 2022, we had cash of approximately $8.8 million. We expect to receive up to approximately an additional $1.8 million under the SBIR Award, including approximately $928 thousand remaining from the May 2022 National Cancer Institute Notice of Allowance for the second year of the SBIR, and up to $870,684 in the third year of the SBIR, although there is no guarantee that we will receive awarded funds. We believe that cash as of September 30, 2022, and SBIR funds received in the second year of the SBIR Award will be sufficient to fund our operating expenses and capital expenditure requirements through the first quarter of 2023. The balance of approximately $870 thousand for the third year of the SBIR is still anticipated although there is no guarantee that these funds will be received. 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

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 precautionary measures intended to help ensure our employees' well-being and minimize business disruptions. 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, or collaborators 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, collaborators, 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 all costs of senior 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 also engage analytical testing laboratories 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 payable within the first year. Subsequent payments are $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. These are funds we had already budgeted for research and development, so do not represent additional spending. We will need to raise additional funds to meet the subsequent payment obligations.

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 their approval, if obtained.

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 and business 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 the approximate amounts of our unaudited results of operations for the periods indicated:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	Change	2022	2021	Change
	(in thousands)					
Operating expenses						
Research and development	$ 3,044	$ 993	$ 2,051	$ 7,546	$ 1,468	$ 6,077
General and administrative	1,910	1,367	543	5,593	1,696	3,897
Total operating expenses	4,954	2,360	2,594	13,139	3,165	9,974
Operating loss	(4,954)	(2,360)	(2,594)	(13,139)	(3,165)	(9,974)
Other income (expense)						
Change in fair value of derivative liabilities	—	—	—	—	(867)	867
Change in fair value of warrant liability	—	(1)	1	—	(6)	6
Grant income	655	32	623	697	89	608
Interest expense	—	(0)	0	—	(95)	95
Interest income	9	0	9	11	0	11
Total other income (expense)	664	31	633	708	(879)	1,587
Net loss	$ (4,290)	$ (2,329)	$ (1,961)	$ (12,431)	$ (4,044)	$ (8,387)

Comparison of the three and nine months ended September 30, 2022 and 2021

Research and development expenses

Research and development, or R&D, expenses increased $2,051 thousand and $6,077 thousand for the three and nine months ended September 30, 2022, respectively, compared to the same periods the prior year. The increases were primarily due to purchases of materials, compensation and related personnel costs which we largely did not have in the 2021 period except for stock compensation expenses until after our IPO in July 2021, and regulatory, purchased services and consulting costs, offset in part by increased grant income and reduced costs related to development of intellectual property.

General and administrative expenses

General and administrative expenses increased $543 thousand and $3,897 thousand for the three and nine months ended September 30, 2022, respectively, compared to the same periods the prior year. The increases were primarily a result of increased expenses for directors and officers liability insurance, compensation and related personnel costs which we largely did not have in the 2021 period except for stock compensation expenses until after our IPO in July 2021, and corporate and other costs of being a public company, offset in part by reduced accounting and audit expenses.

Grant Income

Grant income increased $623 thousand and $608 thousand in the three and nine months ended September 30, 2022, 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 and nine months ended September 30, 2022, did not commence until June 1, 2022, because notice of the second year of the Award was not issued until May 31, 2022.

Change in fair value of derivative liabilities

The change in fair value of derivative liabilities was $0 for the three months ended September 30, 2022 and 2021, compared to $0 in the nine months ended September 30, 2022, and a credit of $867 thousand in the nine months ended September 30, 2021. The derivative liabilities were extinguished at the IPO, when the related notes converted into common stock.

Change in fair value of warrant liability

The fair value of the warrant liability charge was $0 for the three and nine months ended September 30, 2022. In the 2021 periods, there was a credit of $1 thousand for the three months ended September 30, 2021, and $6 thousand for the nine months ended September 30, 2021. The warrants were exercised shortly prior to our IPO and the warrant liability was extinguished at that time.

Interest expense

The charge to interest expense was $0 for the three months ended September 30, 2022 and 2021, and $0 and $95 thousand charged in the nine months ended September 30, 2022 and 2021, respectively. The three $0 amounts reflect conversion of our convertible promissory notes into our common stock in connection with our IPO while the $95 thousand in the nine months ended September 30, 2021, related to the notes prior to conversion.

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 and with funds from our IPO and SBIR Award. Through September 30, 2022, we had received gross cash proceeds of approximately $31.5 million from these sources.

At September 30, 2022, we had cash of approximately $8.8 million. We expect to receive up to approximately an additional $1.8 million under our SBIR Award, including the approximately $928 thousand remaining from the May 2022 National Cancer Institute Notice of Allowance for the second year of the SBIR, and up to $870,684 in the third year of the SBIR. We expect to draw down the second year balance before the end of March 2023 There is no assurance that funds for the third year of the SBIR Award will be received as the U.S. Government has broad authority with respect to expenditures, including those awarded under the SBIR.

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 September 30, 2022, we had cash of approximately $8.8 million. We believe that these funds along with additional funding from year two of our SBIR Award will be sufficient to fund our operating expense and capital expenditure requirements through the first quarter of 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 factors raise substantial doubt about our ability to continue as a going concern. We anticipate that we will require additional capital for additional research, development, and clinical trials, as we seek regulatory approval of our product candidates, for 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 as might preferred equity financing.

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 the approximate amounts of our unaudited cash flows for the periods indicated:

	Nine months ended September 30,	
	2022	2021
	(unaudited) (in thousands)	
Net cash used in operating activities	$ (11,743)	$ (3,666)
Net cash used in investing activities	(73)	(169)
Net cash provided by (used in) financing activities	(220)	25,507
Net decrease in cash	$ (12,036)	$ 21,672

Comparison of the nine months ended September 30, 2022 and 2021

Operating activities

During the nine months ended September 30, 2022, we used cash of $11,743 thousand in operating activities compared to using $3,666 thousand in the nine months ended September 30, 2021. The cash used in operating activities in the 2022 period primarily reflected our net loss of $12,431 thousand, an increase in prepaid expenses and other current assets of $385 thousand and an increase of $488 thousand in grant receivable, offset in part by an increase in accounts payable and accrued expenses of $1,234 thousand and share-based compensation expense of $265 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 nine months ended September 30, 2022, we used cash of $73 thousand in investing activities, primarily for purchases of laboratory and computer equipment, versus $169 thousand of such purchases in the 2021 period.

Financing activities

During the nine months ended September 30, 2022, we used cash of $220 thousand in financing activities, primarily related to additions to deferred offering costs, partly offset by proceeds from an exercise of stock options of $6 thousand.

During the nine months ended September 30, 2021, we obtained $25,507 thousand in cash from financing activities, primarily reflecting proceeds from our IPO offset in part by payments of deferred offering costs.

Contractual obligations and commitments

At September 30, 2022, we had no future minimum lease payments under non-cancelable operating lease commitments. We enter into contracts in the normal course of business with CROs, collaborators, CMOs 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 to date 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. We have committed to fund up to $10 million over the term of the alliance, with $500,000 payable within the first year. Subsequent payments are $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. We will need to raise additional funds to meet the subsequent payment obligations. These are funds we had already budgeted for research and development, so do not represent additional spending. 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. The amounts we pay under the collaboration agreement will be charged as research and development expenses in our statements of operations.

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, 2021, 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. Between 2016 and 2018, we issued restricted stock to directors, management and others which restricted stock vested generally over three years. All restricted stock had vested as of October 31, 2021, and there is no further compensation expense to be recorded in connection with restricted stock. From time to time beginning in June 2020, we have awarded stock options with service-based vesting conditions and recorded share-based compensation expense resulting from those awards as vesting has occurred. 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 vesting 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 $0.07. In March 2020, the appraisal firm estimated that as of December 31, 2019, it was $0.08 per share and in December 2020, it was estimated to be $3.91 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, 2021, 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, 2021, "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." We have engaged a consulting firm to assist us with designing and implementing internal controls appropriate to regulatory and operating requirements. There is no assurance that any controls we implement will prevent fraud or enable accurate or timely financial reporting.

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 $1.235 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, 2021, "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 a computer support firm 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 September 30, 2022 and 2021, 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 September 30, 2022, and December 31, 2021, we had no debt outstanding. We currently, therefore, are not 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 nine months ended September 30, 2022 and 2021, 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 September 30, 2022. 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. We have engaged a consulting firm to assist us with designing and implementing internal controls appropriate to regulatory and operating requirements. There is no assurance that any controls we implement will prevent fraud or enable accurate or timely financial reporting.

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 nine months ended September 30, 2022, 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, 2021, 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;
- 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.

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

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: November 14, 2022

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

Date: November 14, 2022

/s/ Thomas A. Fitzgerald
Thomas A. Fitzgerald
Chief Financial Officer
(Principal Financial and Accounting 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

    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; and

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.

Date: November 14, 2022

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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

    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; and

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.

Date: November 14, 2022

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

Exhibit 32.1

CERTIFICATION 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 September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert Michael Dudley, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his 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: November 14, 2022

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

Exhibit 32.2

CERTIFICATION 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 September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Thomas A. Fitzgerald, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his 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: November 14, 2022

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