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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, 2021

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 15, 2021, the registrant had 12,904,574 shares of Common Stock, $0.0001 par value per share, outstanding.

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

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Summary of Material Risks

Our business is subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks are described more fully elsewhere in this Quarterly Report on From 10-Q and include, but are not limited to, the following:

- We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.
- We will need to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, scale back or discontinue some of our product candidate development programs or commercialization efforts.
- The amount of our future losses is uncertain, and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.
- Our independent public accounting firm has previously expressed substantial doubt about our ability to continue as a going concern.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- Because our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenues.
- Our business is highly dependent on the success of TTX-MC138, our lead candidate which is at the early stages of development. All of our product candidates may require significant additional preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of TTX-MC138 or any of our other product candidates in development.
- Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.
- We may not be successful in our efforts to identify or discover additional product candidates in the future.
- If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of our product candidates.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Our product candidates may cause undesirable side effects or death or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.
- Sales of our products may involve a lengthy sales cycle.
- A variety of factors, including COVID-19 related issues or inadequate funding for the U.S. Food and Drug Admininstration, or FDA, the U.S. Securities and Exchange Commission, or SEC, and other government agencies, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.
- Even if we receive regulatory approval of TTX-MC138 or any of our other product candidates, we will be subject to ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense. We may be

subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

- Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, the violation of which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits.

- Obtaining and maintaining regulatory approval for our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that or of any of our other product candidates in other jurisdictions.

- We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell any products for which we obtain regulatory approval, we may not be able to generate product revenue.

- Health insurance coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

- We expect to rely on third-parties to manufacture and supply materials we require for research and development, preclinical studies and clinical trials which could result in supplies that are limited or interrupted or which may not be of satisfactory quantity or quality or other delays or disruptions.

- We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

- Parties conducting some or all of our product manufacturing may not perform satisfactorily.

- We are highly dependent on others to provide services for certain core aspects of our business.

- If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

- We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products.

- The global pandemic of the novel coronavirus disease, COVID-19, has, and may continue to, adversely impact our business, including our preclinical studies and clinical trials. Dislocations related to the pandemic and the development of vaccines and other treatments for COVID-19 has led to a shortage of animals available for pre-clinical toxicology and other forms of required testing which could cause delays to our Exploratory Investigational New Drug, or eIND, enabling studies or other required testing.

- We will need to grow the size of our organization, and we may experience difficulties managing this growth.

- Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs.

- Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

- Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

- The patents covering our lead candidate, TTX-MC138, are currently issued only in the U.S. and there are no foreign applications pending for this invention at this time. We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

- Our executive officers, directors, principal stockholders and their affiliates exercise significant influence over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

- We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock which may decline.

- 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 may not be able to continue to satisfy requirements of the Nasdaq Capital Market or to maintain a listing of our common stock on the Nasdaq Capital Market.

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 TTX-MC138, our lead product candidate focused on metastatic cancer treatment, and our ability to initiate and complete this trial;

- our ability to expand our drug candidate portfolio through internal research and development or the acquisition or in-licensing of intellectual property assets;

- the impact of the global outbreak of the COVID-19 coronavirus, including the spread of new strains of the virus, on the above-described 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 the above-described preclinical and clinical trial activities;

- the therapeutic benefits, effectiveness and safety of our product candidates;

- our ability to receive regulatory approval for our product candidates in the United States, Europe and other geographies;

- the expected regulatory approval pathway for our product candidates, and our ability to obtain, on satisfactory terms or at all, the financing required to support operations, development, clinical trials, and commercialization of products;
- our reliance on third parties for the planning, conduct and monitoring of clinical trials and for the manufacture of clinical drug supplies and drug product;
- 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 product candidates;
- the market acceptance of our product candidates that are approved for marketing in the United States or other countries;
- our ability to successfully commercialize our product candidates;
- the safety and efficacy of therapeutics marketed by our competitors that are targeted to indications which our product candidates have been developed to treat;
- the impact of natural disasters, global pandemics (including the outbreak of a novel strain of the COVID-19 coronavirus and subsequent spread of new strains of the virus), labor disputes, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations at our manufacturing facilities;
- our ability to utilize our proprietary technological approach to develop and commercialize our product candidates;
- potential collaborators to license and commercialize any product candidates for which we receive regulatory approval in the future 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 upon 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 Part II, Item 1A, “Risk Factors” of this Quarterly Report on Form 10-Q.

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 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 Part II, Item 1A, “Risk Factors” 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 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 statements 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 Part II, Item 1A, “Risk Factors” 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, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this Quarterly Report on Form 10-Q may appear without the ®, TM or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

TRANSCODE THERAPEUTICS, INC.

BALANCE SHEETS

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 22,499,856	$ 828,016
Prepaid expenses and other current assets	2,704,386	3,199
Total current assets	25,204,242	831,215
Fixed assets, net of depreciation	155,610	—
Deferred offering costs	—	224,153
Total assets	$ 25,359,852	$ 1,055,368
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,984,657	$ 369,177
Deferred grant income	220,075	—
Due to related parties	—	35,685
Total current liabilities	2,204,732	404,862
Convertible promissory notes, net of debt issuance costs and debt discount	—	2,086,675
Accrued interest – convertible promissory notes	—	191,687
Derivative liabilities	—	1,751,000
Warrant liability	—	29,376
Total liabilities	2,204,732	4,463,600
Stockholders' equity (deficit):		
Preferred stock – $0.0001 par value; 10,000,000 and - 0 - shares authorized at September 30, 2021, and December 31, 2020, respectively; - 0 - shares issued and outstanding at September 30, 2021, and December 31, 2020	—	—
Common stock – $0.0001 par value, 290,000,000 shares authorized at September 30, 2021, and 20,000,000 shares authorized at December 31, 2020; 12,904,574 and 4,636,216 shares issued and outstanding at September 30, 2021, and December 31, 2020, respectively	1,291	464
Additional paid-in capital	30,669,297	65,949
Subscription receivable	(9,446)	(12,763)
Accumulated deficit	(7,506,022)	(3,461,882)
Total stockholders' equity (deficit)	23,155,120	(3,408,232)
Total liabilities and stockholders' equity (deficit)	$ 25,359,852	$ 1,055,368

See accompanying notes to financial statements.

TRANSCODE THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 992,946	$ 53,936	$ 1,468,457	$ 132,636
General and administrative	1,366,963	185,555	1,696,444	214,967
Total operating expenses	2,359,909	239,491	3,164,901	347,603
Operating loss	(2,359,909)	(239,491)	(3,164,901)	(347,603)
Other income (expense)				
Change in fair value of derivative liabilities	—	(840,000)	(867,000)	(840,000)
Change in fair value of warrant liability	(1,340)	(14,164)	(6,109)	(14,164)
Grant income	31,735	—	88,786	—
Interest expense	(333)	(280,277)	(95,070)	(340,709)
Interest income	141	28	154	114
Total other income (expense)	30,203	(1,134,413)	(879,239)	(1,194,759)
Net loss	$ (2,329,706)	$ (1,373,904)	$ (4,044,140)	$ (1,542,362)
Basic and diluted loss per share				
Net loss	$ (2,329,706)	$ (1,373,904)	$ (4,044,140)	$ (1,542,362)
Weighted-average common shares outstanding	11,526,514	4,636,216	6,932,982	4,636,216
Net loss per share	$ (0.20)	$ (0.30)	$ (0.58)	$ (0.33)

See accompanying notes to financial statements.

TRANSCODE THERAPEUTICS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Subscription Receivable	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Nine months ended September 30, 2020						
Balance, December 31, 2019	4,636,216	$ 464	$ 20,014	$ (12,272)	$ (1,117,989)	$ (1,109,783)
Net loss	—	—	—	—	(41,260)	(41,260)
Interest on subscription receivable	—	—	123	(123)	—	—
Share based compensation	—	—	698	—	—	698
Balance, March 31, 2020	4,636,216	464	20,835	(12,395)	(1,159,249)	(1,150,345)
Net loss	—	—	—	—	(127,198)	(127,198)
Interest on subscription receivable	—	—	245	(245)	—	—
Share based compensation	—	—	699	—	—	699
Balance, June 30, 2020	4,636,216	464	21,779	(12,640)	(1,286,447)	(1,276,844)
Net loss	—	—	—	—	(1,373,904)	(1,373,904)
Interest on subscription receivable	—	—	—	—	—	—
Share based compensation	—	—	31,383	—	—	31,383
Balance, September 30, 2020	4,636,216	$ 464	$ 53,162	$ (12,640)	$ (2,660,351)	$ (2,619,365)
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,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (4,044,140)	$ (1,542,362)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	13,482	—
Share-based compensation expense	146,996	32,780
Change in fair market value of derivative liabilities	867,000	840,000
Non-cash interest expense	39,471	252,819
Change in fair market value of warrant liability	6,109	14,164
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(2,701,186)	(3,200)
Accounts payable and accrued expenses	1,766,148	80,429
Deferred grant income	220,075	—
Payment of amount due to related parties	(35,685)	—
Accrued interest on convertible promissory notes	55,598	87,890
Net cash used in operating activities	(3,666,132)	(237,480)
Cash flows from investing activities:		
Purchase of equipment	(169,092)	—
Net cash used in investing activities	(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 warrants	29,267	—
Proceeds from convertible promissory notes	—	1,190,000
Proceeds from subscription receivable	3,640	—
Payments of deferred offering costs	(860,943)	(61,055)
Net cash provided by financing activities	25,507,064	1,128,945
Net change in cash and cash equivalents	21,671,840	891,465
Cash and cash equivalents, beginning of period	828,016	204,471
Cash and cash equivalents, end of period	$ 22,499,856	$ 1,095,936
Supplemental disclosure of cash flow		
Cash paid during the year for:		
Interest	—	—
Income taxes	—	—
Supplemental disclosure of non-cash investing and financing activities:		
Accrued interest on subscriptions receivable	$ 323	$ 368
Debt discounts associated with derivative liabilities of convertible promissory notes	$ 37,471	$ 304,000
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 12,459
Conversion of convertible promissory notes, including embedded derivative, to common stock	$ 4,991,431	$ —
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 commisions 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 on developing and commercializing innovative drugs for treating metastatic disease. TransCode is preparing for its first clinical study. The Company's lead therapeutic candidate, TTX-MC138, is an oligonucleotide conjugated to an iron oxide nanoparticle designed to be administered by infusion to inhibit the ability of metastatic tumor cells to survive. The goal of the therapy to treat metastatic disease, if approved, is to achieve lifelong regression and long-term patient survival.

Since its founding, the Company has been engaged in organizational activities, including raising capital, and research and development activities. 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.

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 until such time, if ever, that the Company can generate significant revenue from product candidates currently in development. At September 30, 2021, the Company had an accumulated deficit of $7,506,022. At September 30, 2021, the Company had $22,499,856 in cash and cash equivalents. Through September 30, 2021, the Company's primary source of capital was from the sale of convertible promissory notes and equity securities.

On July 13, 2021, the Company completed the initial public offering ("IPO") of its common stock at an initial offering price of $4.00 per share. The Company's common stock commenced trading on the Nasdaq Capital Market on July 9, 2021, 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. The gross proceeds from the IPO, including proceeds from the exercise of the underwriters' option to purchase additional shares, were $28.8 million. 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 and offering costs accrued and unpaid as of June 30, 2021. 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 and accrued interest thereon converted into 1,068,135 shares of Company common stock.

As of the date of these financial statements, management believes that its current cash and cash equivalents and funding from an SBIR Grant awarded the Company in April 2021, are sufficient to fund operations and capital requirements for at least the next 12 months. The Company expects to need to raise additional capital to complete clinical development of, and to commercialize, its product candidates. There is no assurance that such financing will be available when needed or on acceptable terms.

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 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 significantly scale back planned operations or relinquish or otherwise dispose of rights to technologies on unfavorable terms.

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

(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 U.S. generally accepted accounting principles (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, 2021, and its results of operations and its cash flows for the three and nine months ended September 30, 2021 and 2020. 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, 2020, and notes thereto contained in the Company's prospectus dated July 8, 2021, 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 the valuation of share-based compensation, 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.

(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 and stock options, which would result in the issuance of incremental shares of common stock. The computation of diluted net earnings (loss) per shares does not include the conversion or exercise of Contingent Securities that would be antidilutive. The basic and diluted computations of net loss per share for the three and nine months ended September 30, 2021 and 2020, are the same because the effect of the Contingent Securities, if applicable, was antidilutive.

(d) Cash and Cash Equivalents

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. 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). The Company's cash balances at September 30, 2021, were $22,499,856.

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(e) Fair Value of Financial Instruments

The Company's financial instruments at September 30, 2021, and December 31, 2020, included cash and cash equivalents, accounts payable, accrued expenses, convertible notes, derivative liabilities related to the convertible notes and the warrant liability. Cash and cash equivalents and the derivative liabilities are reported at fair value. The recorded carrying amount of accounts payable and accrued expenses reflect their fair value due to their short-term nature. The carrying value of the interest-bearing convertible notes approximates fair value based upon the borrowing rates currently available to the Company for loans with similar terms and maturities.

(f) Research and Development

Research and development costs are expensed as incurred and primarily comprise expenses to discover, research and develop therapeutic candidates. These expenses may include personnel costs, stock-based compensation expense, materials and supplies, allocated facility-related and depreciation expenses, third-party license fees, and costs under arrangements with third party vendors, such as contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and consultants. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as expenses as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered. At September 30, 2021, and December 31, 2020, the Company's outstanding payables to CROs or CMOs were $101,124 and $31,346, respectively.

The Company has entered into various research and development-related contracts with companies both inside and outside of 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.

(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. Grant payments received 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 nonemployees over the period during which services are rendered by such nonemployees until completed. Generally, the Company issues awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company classifies share-based compensation expense in its statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified. Forfeitures are accounted for as they occur.

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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 most recent third-party valuation and the date of the grant. The assumptions used in calculating the fair value of share-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, share-based compensation expense could be materially different. The fair value of future awards will be 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. As an historically private company, the Company has lacked company-specific historical and implied volatility information for its stock. Therefore, it has 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 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) 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 September 30, 2021, and December 31, 2020, 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 September 30, 2021, or December 31, 2020.

(j) 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.

(k) Derivative Liabilities

The Company does not use derivative instruments to hedge exposures to interest rate, market, or foreign currency risks. The Company evaluates all of its financial instruments, including convertible promissory notes, to determine if such instruments contain features that meet the definition of embedded derivatives.

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Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the statement of operations each period. Bifurcated embedded derivatives are classified with the related host contract in the Company's balance sheet.

In connection with the Company's convertible promissory notes, the Company identified certain embedded and freestanding derivatives which it recorded as liabilities on the balance sheets and remeasured to fair value at each reporting date until the derivative was settled. Changes in the fair value of the derivative liabilities are recognized in the statements of operations.

(l) Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process capital stock financings as deferred offering costs until such financings are consummated. After consummation of the financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the statements of operations. As of September 30, 2021, and December 31, 2020, the balances of deferred offering costs were $0 and $224,153, respectively, incurred in connection with the Company's IPO and reported as long-term assets on the accompanying balance sheets. Total deferred offering costs of $934,427 were offset against proceeds received from the IPO and charged to additional paid-in capital.

(m) 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 Financial Accounting Standards Board ("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.

(n) Recent Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40). ASU 2020-06 simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU also simplifies the diluted earnings per share (EPS) calculation in certain areas. The ASU is effective for public business entities that meet the definition of a Securities and Exchange Commission (SEC) filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. For all other entities, the standard will be effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating ASU 2020-06 and assessing the impact of its adoption on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. The amendments in ASU 2019-12 simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and clarifying and amending existing guidance. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating ASU 2019-12 but does not believe the adoption of this standard will have a significant impact on its financial statements.

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In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which supersedes the existing guidance for lease accounting ("Topic 842"). The FASB has issued several updates to the standard which: (i) clarify how to apply certain aspects of the new standard; (ii) provide an additional transition method for adoption of the new standard; (iii) provide a practical expedient for certain lessor accounting; and (iv) amend certain narrow aspects of the guidance. Topic 842 requires the identification of arrangements that should be accounted for as leases by lessees. In general, for lease arrangements exceeding a twelve- month term, these arrangements must be recognized as assets and liabilities on the balance sheet of the lessee. Under Topic 842, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing, while the income statement will reflect lease expense for operating leases and amortization/ interest expense for financing leases. The balance sheet amount recorded for existing leases at the date of adoption of Topic 842 is calculated using the applicable incremental borrowing rate at the date of adoption. While Topic 842 is effective for the Company, the Company has no long-term leases requiring consideration under Topic 842.

(o) Reverse Stock Split

On March 22, 2021, the Board and shareholders of the Company approved a reverse stock 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 conversion or 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 and 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 September 30, 2021, and December 31, 2020. The carrying amount of cash and accounts payable approximated fair value as they are short term in nature. The guidance in ASC 815, Derivatives and Hedging, required that we mark the value of our common stock warrant liability to market and recognize the change in valuation in our statements of operations each reporting period. Determining the warrant liability to be recorded required us to develop estimates to be used in calculating the fair value of the warrant. The fair value of the common stock warrants we issued were estimated based on a Black-Scholes model at the reporting date. The estimated fair value of the warrant liability and the derivative liability ("embedded put features") included in the convertible promissory notes represent Level 3 measurements. The following table details the fair value measurement within the fair value hierarchy of the Company's financial instruments, which includes the Level 3 liabilities:

	Fair value measurements as of December 31, 2020, using:			
	Level 1	Level 2	Level 3	Total
Liabilities				
Derivative liabilities	$ —	$ —	$ 1,751,000	$ 1,751,000
Warrant liability	—	—	29,376	29,376
	$ —	$ —	$ 1,780,376	$ 1,780,376

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At September 30, 2021, the Company had no derivative liabilities or warrant liability.

During the three and nine months ended September 30, 2021 and 2020, there were no transfers between Level 1, Level 2 and Level 3.

A summary of the changes in the fair value of Level 3 financial instruments for the nine months ended September 30, 2021, is as follows:

	Level 3
Balance, December 31, 2020	$ 1,780,376
Changes in fair value of derivative liability	867,000
Extinguishment of liability on conversion of Notes	(2,647,376)
Changes in fair value of warrant liability	6,109
Extinguishment of liability on exercise of warrants	(6,109)
Balance, September 30, 2021	$ —

For further discussion of the derivative liabilities, see Note 8. For further discussion of the warrant liability, see Note 10.

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	September 30, 2021	December 31, 2020
Prepaid operating expenses	$ 46,283	$ —
Contract manufacturers and research organizations	164,145	—
Insurance premiums	2,002,983	—
Deposits	9,410	3,199
Other current assets	481,565	—
	$ 2,704,386	$ 3,199

(5) Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	September 30, 2021	December 31, 2020
Professional and consulting fees	$ 107,386	$ 273,294
Research and development expenses	118,557	51,806
Accrued license payments	3,570	42,300
Operating expenses	56,625	1,777
Insurance premiums	1,664,340	—
Payroll and benefits	34,179	—
	$ 1,984,657	$ 369,177

See Note 7 for further information regarding the accrued license payments.

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(6) Deferred 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 $2,392,845 over three years to fund a two-phased research partnership between the Company and Massachusetts General Hospital. In May 2021, the Company received the first year funding of $308,861 which it recorded as Deferred Grant Income. Income under the Grant is recognized as work under the Grant is completed. The Company recognized $31,735 of Grant Income for the three months ended September 30, 2021, and $88,786 for the nine months ended September 30, 2021.

(7) 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 $6,210 and the Company pays an additional amount for its allocated share of operating expenses currently assessed at $15 per square foot or $3,105 per month. The agreement is for one year, includes an option to extend the agreement upon the mutual agreement of the parties, and is cancelable anytime upon 90 days' notice. The lease commitment as of September 30, 2021, through February 28, 2022, amounts to $46,575. In March 2020, the Company entered into an agreement with the Pagliuca Harvard Life Lab whereby the Company rented one laboratory bench and the right to use certain common facilities at the Life Lab. In March 2021, the Company terminated the arrangement with the Life Lab.

(b) License Agreement

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

At September 30, 2021 and December 31, 2020, the Company had accrued $3,570 and $42,300, respectively, in license payments under the terms of the License, included in accounts payable and accrued expenses. The amounts due at September 30, 2021, and at December 31, 2020, have been paid.

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, 2021, and December 31, 2020, no milestone events had been achieved.

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In addition to milestone payments, royalties shall be paid to Licensor 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.

Option Agreement

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. 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.

(c) 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 $2,412,000.

(d) 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, 2021, and December 31, 2020, the Company did not have any pending legal actions.

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(e) 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, 2021, and December 31, 2020.

(f) Risks and Uncertainties

In December 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19, surfaced in Wuhan, China, and subsequently spread worldwide, including to Eastern Massachusetts where the Company's primary office and laboratory space is located. The coronavirus pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations directly or through parties on whom we depend will also depend on future developments, which are highly uncertain and cannot be predicted with confidence. The outcome of these events could delay the Company's plans, increase its operating expenses and have a material adverse effect on its financial results.

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 $480,753 was held by the receiving bank pending investigation and resolution. At September 30, 2021, the latter amount was included in the Other Current Assets; it was recovered in full on October 15, 2021. Management believes this incident had an immaterial impact on the Company's financial condition and is reviewing its computer-related policies to implement additional defenses.

(8) Convertible Promissory Notes

From May 2018 through May 2020, the Company issued 14 convertible promissory notes ("Notes") having an aggregate principal amount of $2,240,000 with an interest rate of 6% per annum. These Notes and accrued interest thereon converted into 1,068,135 shares of the Company's common stock in connection with the Company's IPO. As of the IPO (July 13, 2021) and at December 31, 2020, total accrued interest on the Notes was $247,285 and $191,687, respectively.

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Convertible promissory notes at the time of the IPO comprised the following:

Note Identifier	Issue Date	Principal Amount	Accrued Interest at July 13, 2021	Accrued Interest at December 31, 2020
Note One	May 2, 2018	$ 500,000	$ 92,548	$ 80,137
Note Two	June 26, 2018	$ 50,000	$ 8,803	$ 7,562
Note Three	March 2, 2019	$ 100,000	$ 13,249	$ 10,767
Note Four	March 5, 2019	$ 50,000	$ 6,625	$ 5,466
Note Five	March 8, 2019	$ 50,000	$ 6,707	$ 5,384
Note Six	March 15, 2019	$ 50,000	$ 6,567	$ 5,326
Note Seven	March 20, 2019	$ 50,000	$ 6,534	$ 5,293
Note Eight	November 7, 2019	$ 100,000	$ 9,205	$ 6,723
Note Nine	November 7, 2019	$ 100,000	$ 8,942	$ 6,460
Note Ten	February 17, 2020	$ 1,000,000	$ 75,806	$ 50,984
Note Eleven	April 3, 2020	$ 40,000	$ 2,780	$ 1,790
Note Twelve	May 8, 2020	$ 50,000	$ 3,192	$ 1,951
Note Thirteen	May 8, 2020	$ 50,000	$ 3,192	$ 1,951
Note Fourteen	May 15, 2020	$ 50,000	$ 3,135	$ 1,893

The unamortized amounts of debt issuance costs and debt discounts at the IPO and December 31, 2020, are:

	July 13, 2021	December 31, 2020
Principal amount of convertible promissory notes	$ 2,240,000	$ 2,240,000
Less unamortized debt issuance costs	(6,002)	(8,002)
Less unamortized debt discounts	(107,852)	(145,323)
Convertible promissory notes, net	$ 2,126,146	$ 2,086,675

Settlement of the Notes required that, at the closing of a Qualified Financing (as defined) the Company provide the holder with a variable number of shares with an aggregate fair value determined by reference to the debt principal and accrued but unpaid interest. In this scenario, the value that the holder receives at settlement does not vary with the value of the Company's common stock, so the settlement provision was not a typical conversion option. Rather, the share settlement feature was considered a contingent redemption provision (i.e., a contingent embedded put). The Company evaluated the embedded put features in accordance with ASC 815-15-25. The embedded puts are not clearly and closely related to the debt host instrument and therefore have been separately measured at fair value, with subsequent changes in fair value recognized in the statement of operations.

Management used a scenario-based analysis to estimate the fair value of the embedded put features upon issuance of the Notes. The original values of the embedded put features were recorded as a debt discount to the Notes which discount is amortized over the life of the Notes as non-cash interest expense during the reporting periods.

The IPO constituted a Qualified Financing. At the IPO and December 31, 2020, the fair value of the derivative liability was $2,618,000 and $1,751,000, respectively. Between December 31, 2020, and the IPO, the Company recorded a decrease in fair value of the derivative liability of $867,000.

In the year ended December 31, 2020, the Company amortized debt issuance costs of $10,538 to interest expense. In 2021, through the IPO, the Company amortized $2,000 of debt issuance costs to interest expense.

On the IPO, the full principal amount of Notes outstanding of $2,240,000, the full amount of derivative liabilities associated with the Notes of $2,618,000, as well as accrued interest of $247,285, converted into 1,068,135 shares of common stock. In connection with the conversion of the Notes, the balances of debt discount and debt issuance costs, in the amounts of $107,852 and $6,002, respectively, were also eliminated.

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(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, 2021, and December 31, 2020, the Company had issued and outstanding 4,636,216 shares of restricted common stock subject to forfeiture until vested. At those dates, 4,617,287 shares and 4,489,738 shares, respectively, of restricted common stock had vested. Of the 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. One subscription receivable in the principal amount of $3,290 and accumulated interest was repaid in April 2021. At September 30, 2021, and December 31, 2020, the principal balances of subscriptions receivable was $8,400 and $11,690, respectively, and accrued interest was $1,046 and $1,073, respectively. The Preferred Stock is undesignated; no shares of Preferred Stock have been issued.

The following table lists information about unvested restricted common stock.

Unvested restricted common stock at December 31, 2020	146,483
Shares issued	—
Shares vested	(127,554)
Unvested restricted common stock at September 30, 2021	18,929

Our IPO was completed on July 13, 2021, in which we 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 we 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.

(b) Common Stock

i. Dividends

Subject to the rights of holders of any Preferred Stock, holders of the 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, 2021 and 2020, or 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.

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(10) Warrants

In connection with the May 2, 2018, issuance of the Convertible Promissory Note designated as "Note One" (see Note 8), the Company agreed to pay a cash fee to the finder involved in the sale and to issue to the finder warrants to purchase shares of the Company's common stock. The number of shares of common stock subject to the warrants is equal to five percent of the number of shares of Common Stock into which Note One converts. The exercise price is the conversion price applicable on conversion of the Note. The number of shares of Common Stock to be issued to the holder of the Note on conversion of the Note is equal to the principal amount of the Note, plus accrued but unpaid interest to the date of conversion, divided by the applicable conversion price. The applicable conversion price is equal to the price paid for the Company's equity securities in a Qualified Financing (as defined) less a discount. The discount ranges from 20% to 30% depending on the length of time after the investment to complete the Qualified Financing.

Pursuant to ASC 718, the obligation to issue the Warrants was accounted for as a liability until exercise or expiration as they are an award that embodies an unconditional obligation to issue an undeterminable number of shares for a fixed monetary amount known at inception. Upon issuance, the liability was reclassified to equity.

The obligation to issue Warrants has been recorded at fair value on inception date and was remeasured at each reporting period until exercise or expiration. The compensation cost recognized for a liability-classified award equals the amount for which the award is settled. Therefore, the Company measured the obligation to issue warrants at fair value on May 2, 2018, and remeasured fair value at each reporting period until the Warrants were exercised.

Regardless of the applicable conversion price resulting from application of the foregoing process, the applicable conversion price could not exceed that price per share that equates to a $15 million pre-money valuation. The Warrants were exercised in full the day prior to the IPO at an exercise price of $2.32 per share. Also, at the time of exercise, in addition to recording the aggregate exercise price of the warrants, the Company also extinguished the balance of the warrant liability.

A summary regarding the fair value of the warrant liability is as follows:

	Warrant Liability
Fair value at December 31, 2020	$ 29,376
Change in fair value	6,109
Fair value at July 12, 2021 (date of exercise)	35,485
Extinguishment of warrant liability on warrant exercise	(35,485)
Fair value at September 30, 2021	$ —

The fair value of the Company's warrant liability was calculated using the Black-Scholes model and the following assumptions:

	As of July 13, 2021	As of December 31, 2020
Fair value per share of Company's common stock	$ 3.94	$ 3.91
Dividend yield	0.0 %	0.0 %
Expected volatility	88.0 %	84.0 %
Risk free interest rate	0.6 %	0.3 %
Expected life (years)	3.44	4.67
Fair value of warrants	$ 35,485	$ 29,376

Underwriter 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

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five-year term and are not exercisable prior to January 9, 2022. All of the warrants were outstanding at September 30, 2021. The Company accounts for the warrants as a component of stockholders' equity.

(11) Share-Based Compensation

Since inception, the Company has 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 is recorded for the periods in which such shares vest. The vesting period for restricted stock is generally two to three years.

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 has determined not to make any further awards under the 2020 Plan following the closing of the IPO. In March 2021, our 2021 Stock Option and Incentive Plan (the "2021 Plan") was approved by our Board and our stockholders and became effective upon the effectiveness of our IPO. The 2021 Plan provides for the issuance of options or other awards to purchase up to 2,500,000 shares of the Company's Common Stock.

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

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

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In 2020, the Board awarded options to purchase 1,756,279 shares of Common Stock under the Plan, all of which were outstanding at September 30, 2021. In January 2021, the Board awarded options to purchase 36,393 shares of Common Stock under the Plan, all of which were outstanding at September 30, 2021. No awards have been made under the 2021 Plan.

At September 30, 2021, there were 891,304 options outstanding under the 2020 Plan that were vested and exercisable. Information about options to purchase Common Stock of the Company under the 2020 Plan is as follows:

	Number of shares	Weighted average exercise price per share	Weighted average contractual term (years)
Outstanding at December 31, 2019	—	—	—
Granted	1,756,279	$ 0.25	5.9
Exercised	—	—	—
Forfeited	—	—	—
Outstanding at December 31, 2020	1,756,279	$ 0.25	5.9
Granted	36,393	$ 3.91	5.5
Exercised	—	—	—
Forfeited	—	—	—
Outstanding at September 30, 2021	1,792,672	$ 0.32	5.9

The intrinsic value of the outstanding options as of September 30, 2021, was $4,786,434.

Option valuation

The assumptions that the Company used to determine the grant-date fair value of options granted in the three and nine months ended September 30, 2021, (no options were granted in the three months ended September 30, 2021) were as follows:

	Nine months ended September 30, 2021
Risk-free interest rate	0.59 %
Expected term (in years)	6.0
Expected volatility	97.20 %
Expected dividend yield	— %
Fair value per share of underlying stock	$ 3.91

The weighted average grant date fair value of the options granted in 2021 was $3.01 per share.

The Company recorded share-based compensation expense of $64,052 and $146,996 during the three months and nine months ended September 30, 2021, respectively. Share-based compensation in the three months ended September 30, 2021, was entirely related to stock options. Share-based compensation in the nine months ended September 30, 2021, comprised $145,599 related to stock options and $1,397 related to restricted stock. The remaining compensation costs to be recognized on the stock options is approximately $279,166 over approximately 2.15 years.

(12) Net Loss Per Share

The Company reported net losses for the three and nine months ended September 30, 2021 and 2020. Basic and diluted net loss per share attributable to common stockholders are the same for all periods in which the Company reported losses because shares issuable on conversion of all convertible promissory notes, upon exercise of all warrants, and upon exercise of vested stock options have been excluded from the computation of diluted weighted-average shares outstanding because their inclusion would have been antidilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Basic earnings (loss) per share				
Numerator				
Net income (loss)	$ (2,329,706)	$ (1,373,904)	$ (4,044,140)	$ (1,542,362)
Denominator				
Weighted-average common shares outstanding	11,526,514	4,636,216	6,932,982	4,636,216
Net earnings (loss) per share	$ (0.20)	$ (0.30)	$ (0.58)	$ (0.33)

(13) Income Taxes

The Company's income tax benefit (expense) was $0 for the three and nine months ended September 30, 2021, and 2020. The Company has recorded a full valuation allowance against its net deferred tax assets as of September 30, 2021, and December 31, 2020, 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 months ended September 30, 2021 and 2020, was fully offset by changes in the valuation allowance.

As of September 30, 2021, and December 31, 2020, 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.

(14) 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 remaining unreimbursed at September 30, 2021, and December 31, 2020, is $0 and $35,685, respectively. The Company reimbursed these amounts during the three months ended September 30, 2021.

On approximately April 26, 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.

(15) Subsequent Events

For its financial statements as of September 30, 2021, the Company evaluated subsequent events through November 15, 2021, the date on which those financial statements were issued and concluded there are none for purposes of the financial statements.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the "Financial Statements" section of this Quarterly Report on Form 10-Q including the related notes appearing elsewhere in this Quarterly Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

TransCode Therapeutics is an RNA oncology company, created on the belief that cancer can be defeated 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 with the potential to make available a broad array of previously undruggable targets in the human genome. To date, use of RNA for therapy has been limited due to three delivery-related challenges: protecting the RNA from being dismantled by the immune system; maintaining stability so the molecule has time to do its job; and penetrating the targeted organs and cells. We believe these challenges have led researchers to focus on other approaches to cancer therapeutics. Our strategy seeks to overcome these delivery challenges by repurposing a particle used in humans extensively for imaging purposes to now deliver synthetic RNA molecules (called oligonucleotides) to cancer cells.

We utilize a modular drug design employing tools from the drug discovery toolbox we have created to develop product candidates that we believe can efficiently deliver RNA therapeutics to genetic targets. There are four distinct RNA strategies that we are developing to treat cancer including RNA interference, or RNAi, Pattern Recognition Receptors, or PRRs, Clustered Regularly Interspaced Palindromic Repeats, or CRISPR, and messenger RNA, or mRNA, vaccines. The first approach we are developing is using RNAi to "silence" or turn off the production of specific genes that cause cancer. RNAi is a natural biological process that regulates gene expression by "interfering" with mRNA, the carrier of DNA's instructions for making new proteins. To date, we have utilized this approach to develop novel product candidates for treatment of metastasis and additional therapeutic areas in oncology. Our lead therapeutic candidate, TTX-MC138, is focused on treating metastatic cancer which has been shown to cause approximately 90% of all cancer deaths. TTX-MC138 targets microRNA-10b, or miR-10b, believed to be a critical driver of metastatic progression in a variety of solid tumors. We believe that TTX-MC138 has the potential to produce regression without recurrence in a range of cancers including breast, pancreatic, ovarian and colon cancer, glioblastomas and others. Our other RNAi therapeutic candidates are TTX-siPDL1 and TTX-siLIN28b which focus on treating cancer by targeting PD-L1, and Lin28b, respectively. The second RNA approach we are developing targets the retinoic acid-inducible gene I (RIG-I), a cytosolic nucleic acid sensing Pattern Recognition Receptor of the innate immune system. Our therapeutic candidate, TTX-RIGA, is intended to induce RIG-I activation , potentially provoking an immune response against cancer. We are conducting pre-clinical studies with TTX-SiPDL1, TTX-Lin28b and TTX-RIGA. Our very early discovery candidates, TTX-CRISPR and TTX-mRNA, are designed to treat cancer using the RNA approaches of CRISPR and mRNA vaccine technologies. 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 exploring the Lin28b technology under an option to license this 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 asset meet our criteria for addition to 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 inform treatment of patients using RNA therapeutics. Under our 2018 license with MGH, we have licensed a patented microRNA profiling assay with the potential to detect expression of microRNAs in patient blood and tissue samples. We intend to optimize this diagnostic test to detect miR-10b in cancer patients as our first commercial testing product. If approved, this test could be used as a screening assay to detect metastasis in a variety of tumor types. 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.

Recent 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 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 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 as intended and supports clinical evaluation of TTX-MC138. In addition, the MGH investigation describes a microdosing PET-MRI approach that can be used to measure TTX-MC138 biodistribution in cancer patients and its delivery to clinical metastases. The capacity to carry out microdosing PET-MRI studies in patients under an Exploratory Investigational New Drug, or eIND, application could be important because it has the potential to facilitate FDA authorization of initial human studies. This research, published by Dr. Medarova, our Chief Technology Officer and scientific co-founder, describes what we believe is a more effective approach to demonstrate delivery of TTX-MC138 in metastatic cancer patients. Since the PET technique is sensitive enough to determine the concentration of radiolabeled drug in the sub-picomolar range, microgram quantities of the radiolabeled drug are generally sufficient to perform such a study in humans. We believe this capability has significant advantages in the initial phases of drug development. Because the low mass of the radiolabeled drug does not induce reactions in humans, we believe the regulatory process will be less complex.

Dr. Medarova's paper describes methods for the radiolabeling of TTX-MC138 with Cu-64 and its detection by PET-MRI. It also suggests that the radiolabeling does not impact tumor cell uptake and the ability of TTX-MC138 to engage its target. Finally, the paper shows that the biodistribution of Cu-64 labeled TTX-MC138, when injected at a microdose, reflects its biodistribution at a therapeutic dose. These key findings are expected to enable a microdosing study with TTX-MC138 in patients. We believe that a microdosing study has numerous advantages over our original Phase 0 trial design, the intent of which was to dose patients with a single therapeutic dose of TTX-MC138 and image its delivery by MRI. Specifically, a microdosing study as compared to the original Phase 0 study design:

(i) allows more precise quantitation of TTX-MC138 delivered to the metastatic lesions, due to its higher sensitivity and quantitative accuracy. By contrast, imaging of drug delivery by MRI 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 uptake and clearance from vital organs. By contrast, measurement of TTX-MC138 delivery by MRI, as envisioned in the original Phase 0 trial design, would only allow us to assess drug 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, it may be possible to derive a more precise calculation of drug concentration in the metastatic lesions over time and then correlate that dose 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 accumulate TTX-MC138.

Due to the benefits we believe we can derive from a microdosing Phase 0 trial and enabled by the new studies described in *Cancer Nanotechnology*, we now intend to pursue a microdosing Phase 0 trial for our First in Human (FIH) clinical study. In addition to the advantages described above, we also believe the timeline to complete this study will more closely align with the timeline planned for the original Phase 0 study. We have targeted submission of the eIND for the microdosing study in the first half of 2022.

Success in the microdosing study could also validate delivery generally for our TTX pipeline which potentially opens-up additional relevant RNA targets that have been previously undruggable. Concurrent with the Phase 0 study, we expect to complete additional studies to support an IND for a Phase I clinical trial with TTX-MC138 and then file the IND in the second half of 2022 as originally planned.

In the microdose Phase 0 study, we plan to enroll 10 patients with late-stage metastatic breast cancer, infuse a single microdose of radiolabeled TTX-MC138, and use PET-MRI to quantifiably measure its delivery to metastatic lesions and other tissues in the body.

We plan to conduct the clinical portion of the study at the Henri and Belinda Termeer Center for Targeted Therapies at MGH as originally planned. The radiolabeling and PET-MRI studies are expected to be carried out at the Institute for Innovation in Imaging (I3) at MGH. The I3 is a multidisciplinary and translational molecular imaging lab focused on the invention of novel molecular probes and their broad applications in cardiovascular, pulmonary, renal and hepatic diseases, as well as in cancer. Their research spans novel chemistry technologies from advanced MRI and PET imaging in animal models to applications in humans.

SBIR Award

In April 2021, we received a Fast-Track Small Business Innovation Research, or SBIR, award from the National Cancer Institute. The Award is expected to provide $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. Funds are expected to be paid out as follows: $308,861 in the first year; $1,213,387 in the second year; and $870,597 in the third year. First year funds were received in May 2021. If we achieve the milestones associated with a particular stage sooner than scheduled at the time of the award, we may receive the funding for the subsequent stage sooner than originally scheduled.

In the 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 the development of a method for and validation of the use of qRT-PCR to measure miR-10b expression in patient blood and tissue samples. qRT-PCR is often considered the gold standard for quantifying circulating miRNAs with high sensitivity and specificity and with a wide analytical measurement range. This validated test was used to identify the threshold of miR-10b that would be considered a positive expression of miR-10b in samples from metastatic cancer patients. An expected criterion for patient inclusion in our Phase 0 First-in-Human study is to enroll only patients with a positive expression of miR-10b. We are currently preparing our request for the next tranche of funding under this Award.

Financial Operations Overview

Since our inception in January 2016, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, securing intellectual property rights, conducting research and development activities and preparing for manufacturing clinical-trial quantities of our lead product candidate. 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, 2021, we had received gross proceeds of $31.0 million from the July 2021 initial public offering of our common stock and from borrowings under convertible promissory notes obtained between 2018 and 2020.

We have incurred significant operating losses since inception. Our net losses were $4.0 million and $2.3 million for the nine months ended September 30, 2021, and the year ended December 31, 2020, respectively. At September 30, 2021, we had an accumulated deficit of $7.5 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 in-license additional product candidates;
- expand our infrastructure and facilities to accommodate increased 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 the sale 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 in-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, 2021, we had cash and cash equivalents of $22.5 million. We believe that these amounts will enable us to fund our operating expenses and capital expenditure requirements through December 2022. 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. Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations. See “Liquidity and capital resources.”

Impact of the Novel Coronavirus (COVID-19) Pandemic

Since it was reported to have surfaced in December 2019, a novel strain of coronavirus, or COVID-19, has spread across the world and has been declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have intensified and governments around the world, including in the United States, Europe and Asia, have implemented severe travel restrictions, social distancing requirements, stay-at-home orders and have delayed the commencement of non-COVID-19-related

clinical trials, among other restrictions. As a result, the current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. economy and in financial markets. We expect that COVID-19 precautions and effects will directly or indirectly impact the timeline for some of our preclinical studies and possibly our planned clinical trials. We are continuing to assess the potential impact of the COVID-19 pandemic on our current and future business and operations, including our expenses, preclinical studies and clinical trials, as well as on our industry and the healthcare system.

As a result of the outbreak, many companies have experienced disruptions in their operations and in markets served. To date, we have initiated some precautionary measures and we may take additional temporary precautionary measures intended to help ensure our employees' well-being and minimize business disruption. These measures include devising contingency plans and securing additional resources from third-party service providers. Certain of our third-party service providers have also experienced shutdowns or other business disruptions. We are continuing to assess the impact of the COVID-19 pandemic on our current and future business and operations, including our expenses 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, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when, if ever, we will generate 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, engaged in the conduct of our drug discovery efforts, preclinical studies, and clinical trials, and 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-related costs, depreciation and other facilities-related expenses, which may include rent and utilities.

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

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

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

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 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;
- establishing an appropriate safety and efficacy profile with IND enabling studies;
- the timing and terms of regulatory approvals, if any, to conduct clinical trials;
- the number of sites needed to complete clinical trials, the number of patients needed to conduct 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 to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors resulting from the COVID-19 pandemic or similar public health crisis or for any other reason; and
- maintaining an acceptable safety profile of our product candidates following approval, if any, of our product candidates.

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

General and administrative expenses

General and administrative expenses consist primarily of salaries, benefits, travel and other related costs, including share-based compensation expense, for personnel serving in executive, business development, finance, human resources, legal, information technology, pre-commercial and support personnel functions. General and administrative expenses may also include direct and allocated facility-related costs as well as corporate and office expenses, insurance costs and professional fees for legal, patent, consulting, investor and public relations, accounting, tax and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our research activities and development of our product candidates and prepare for potential commercial activities including possible partnerships for the sales, marketing and distribution of approved product candidates, if any. 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 as well as the costs of additional personnel in these areas. 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.

We recently 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 has consisted primarily of interest accrued on our convertible promissory notes and charges for amortizations of debt discount related to the embedded derivative element of our convertible promissory notes and of debt issuance costs. Since the

Notes converted into shares of common stock concurrent with our initial public offering, we will no longer incur interest expense on these Notes.

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 low interest rates earned on those balances.

Change in fair value of derivative liabilities

Our convertible promissory notes provided for conversion into our common stock at a discount which conversion feature met the accounting definition of a derivative instrument. We classified this derivative instrument as a liability on our balance sheet. While the Notes were outstanding, we remeasured fair value of this derivative liability at each reporting date and recognized any changes in fair value as other income (expense) in our statement of operations. Following conversion of the Notes into common stock concurrent with our initial public offering, we no longer have derivative liabilities.

Gains related to conversion of convertible promissory notes and exercise of warrants

We estimated that the fair value of the shares of our common stock issued in connection with the conversion of our convertible promissory notes in the initial public offering is less than the carrying value of these Notes, including related liabilities, that were extinguished on conversion. The difference between our estimated fair value of the shares and the carrying value of the Notes and Note-related liabilities was approximately $0.7 million. This difference represents a non-cash gain to our equity recorded at the time of conversion. There was a comparable non-cash expense related to the exercise of the warrants in connection with the initial public offering. We estimate the warrant-related expense to be approximately $15 thousand.

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 involved in the grant are recorded as deferred grant income on our balance sheet. Grant income is recognized in our statements of operations as and when earned for the performance of the specific research and development activities for which the grants are designated. Grant income earned in excess of grant payments received is recorded as grant receivable on our balance sheet.

Results of operations

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

	Three Months Ended Sept 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
	(in thousands)					
Operating Expenses						
Research and development	$ 993	$ 54	$ 939	$ 1,468	$ 133	$ 1,335
General and administrative	1,367	185	1,182	1,696	215	1,481
Total operating expenses	2,360	239	2,121	3,165	348	2,817
Loss from operations	(2,360)	(239)	(2,121)	(3,165)	(348)	(2,817)
Other Income (expense)						
Change in fair value of derivative liability	—	(840)	840	(867)	(840)	(27)
Change in fair value of warrant liability	(1)	(14)	13	(6)	(14)	8
Grant income	31	—	31	89	—	89
Interest expense	—	(281)	281	(95)	(340)	245
Interest income	—	—	—	—	—	—
Total other income (expense)	30	(1,135)	1,165	(879)	(1,194)	315
Net loss	$ (2,330)	$ (1,374)	$ (956)	$ (4,044)	$ (1,542)	$ (2,502)

Comparison of the three and nine months ended September 30, 2021 and 2020

Research and development expenses

Research and development, or R&D, expenses increased $939 thousand and $1.3 million for the three and nine months ended September 30, 2021, 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 did not have in the 2020 periods except for stock compensation expenses, license fees, costs related to development of intellectual property, and lab facility expenses, offset in part by decreased consulting expenses.

General and administrative expenses

General and administrative expenses increased $1.2 million and $1.5 million for the three and nine months ended September 30, 2021, 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 did not have in the 2020 periods except for stock compensation expenses, investor relations and other costs of being a public company, and expenses for accounting, audit and tax services.

Grant Income

Grant income of $31 thousand and $89 thousand in the three and nine months ended September 30, 2021, respectively, was recognized under an NIH grant awarded in April 2021 to fund certain costs related to studies to advance our lead therapeutic candidate into clinical trials. No grant income was recognized in those periods in the prior year.

Change in fair value of derivative liabilities

The change in the fair value of derivative liabilities was $0 for the three months ended September 30, 2021, and negative $867 thousand in the nine months ended September 30, 2021.

Change in fair value of warrant liability

The change in the fair value of the warrant liability was negative $1 thousand for the three months ended September 30, 2021, and negative $6 thousand in the nine months ended September 30, 2021. We issued warrants to purchase shares of our common stock in consideration for finder's services in connection with a sale of one of our convertible promissory notes in 2018. We classified these warrants as a liability on our balance sheets which we remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability were recognized as a component of other income (expense) in our statements of operations. The warrants were exercised shortly prior to the our initial public offering. Thereafter, there will be no liability related to these warrants.

Interest expense

Interest expense was nearly $0 for the three months ended September 30, 2021, compared to $281 thousand in the 2020 period. Interest expense was $95 thousand for the nine months ended September 30, 2021, compared to $340 thousand for the same period the prior year. The decreases in the periods ended September 30, 2021, compared to the 2020 periods reflect conversion of our convertible promissory notes in connection with our IPO, and the agreement by noteholders to cease interest acccrual at May 31, 2021.

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, this year, with funds from our initial public offering and SBIR Award. Through September 30, 2021, we had received gross cash proceeds of $31 million from these sources.

As of September 30, 2021, we had cash and cash equivalents of $22.5 million.

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 new intellectual property and maintain, expand and protect our intellectual property portfolio.

At September 30, 2021, we had cash and cash equivalents of $22.5 million. We believe that these funds will enable us to fund our operating expenses and capital expenditure requirements through December 2022. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We anticipate that we will require additional capital for additional research, development, clinical trials, as we seek regulatory approval of our product candidates, company operations, and for in-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, which will vary depending on where and how we choose to commercialize.

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 are able to establish;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the efficiency with which we operate our business.

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

If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash flows

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

	Nine months ended September 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (3,666)	$ (238)
Net cash used in investing activities	(169)	—
Net cash provided by financing activities	25,507	1,129
Net increase in cash and cash equivalents	$ 21,672	$ 891

Comparison of the nine months ended September 30, 2021 and 2020

Operating activities

During the nine months ended September 30, 2021, we used cash of $3,666 thousand in operating activities compared to using $238 thousand in the same period the prior year. The cash used in operating activities in the nine months ended September 30, 2021, primarily reflected our net loss of $4,044 thousand and an increase in prepaid expenses and other current assets of $2.7 million, offset in part by an $867 thousand gain from the changed fair market value of derivative liabilities, an increase of $1.8 million in accounts payable and accrued expenses, $220 thousand from deferred grant income, and increased share-based compensation expense of $147 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, 2021, we used cash of $169 thousand in investing activities, primarily purchases of laboratory equipment. No such purchases were made in the 2020 period.

Financing activities

During the nine months ended September 30, 2021, we obtained cash of $25.5 million from financing activities, primarily our initial public offering.

During the nine months ended September 30, 2020, we obtained cash from financing activities of $1.1 million, primarily from borrowings under convertible promissory notes.

Contractual obligations and commitments

As of September 30, 2021, we had no future minimum lease payments under non-cancelable operating lease commitments. We enter into contracts in the normal course of business with CMOs, CROs and other third parties for the manufacture of our product candidates and to support clinical trials and preclinical research studies and testing and for other purposes. These contracts are generally cancelable by us. Payments due upon cancellation 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.

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 appearing in our prospectus of July 8, 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 will compare the payments made to each service provider to the estimated progress towards completion of the related project. Factors that we will consider in preparing these estimates include materials delivered or services provided, the number of patients enrolled in studies, milestones achieved, and other criteria related to the efforts of these vendors. These estimates will be subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, we will 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 the service 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. We make estimates of our accrued expenses as of each balance sheet date in the financial statements 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 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 share-based awards granted to employees and directors based on the fair value of the underlying award on the date of the grant. We recognize the corresponding compensation expense of those awards over the requisite service period, generally the vesting period of the respective award. As of September 30, 2021, we had issued restricted stock and stock options, each with service-based vesting conditions, and recorded share compensation expense resulting from those awards as vesting 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 granted to consultants and non-employees, we recognize compensation expense over the period during which services are rendered by such consultants and non-employees until completed.

Determination of the fair value of common stock

As there has been no public market for our common stock prior to our initial public offering, the estimated fair market 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 market 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 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 market 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 market 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 initial public offering, or 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 a public trading market for our common stock is established after our initial public offering, we do not expect it to be necessary thereafter for our board to estimate the fair market value of our common stock in connection with our accounting for share-based awards that we may grant, as 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.

Awards granted

The following table sets forth the number of shares of restricted stock we granted from January 11, 2016, through October 7, 2018 (the date of the last grant of restricted stock), the per share purchase prices of such shares, and the estimated fair value per share of the awards on the date of grant:

Grant Date	Number of shares subject to award	Per share purchase price of restricted stock	Per share estimated fair value of award on grant date
February 1, 2016	3,245,081	$ 0.0001	$ 0.0001
April 1, 2016	36,393	$ 0.0001	$ 0.0001
August 17, 2016	139,508	$ 0.0001	$ 0.0001
June 1, 2017	812,787	$ 0.0001	$ 0.0001
June 1, 2017[(1)]	(594,427)	$ 0.0001	$ 0.0001
June 12, 2017	600,491	$ 0.0001	$ 0.0001
July 15, 2017	211,991	$ 0.0001	$ 0.0001
August 28, 2017	184,393	$ 0.0001	$ 0.0001
December 11, 2017[(1)]	(1,024,779)	$ 0.0001	$ 0.0001
January 22, 2018	670,246	$ 0.0001	$ 0.0001
July 1, 2018[(2)]	127,377	$ 0.0001	$ 0.0660
October 1, 2018	49,889	$ 0.0660	$ 0.0660
October 7, 2018	177,266	$ 0.0660	$ 0.0660

(1) Cancellations

(2) For restricted stock granted on July 1, 2018, prior to receipt in November 2018 of the report of fair value of our common stock as of June 30, 2018, our board of directors determined that the fair value of our common stock was $0.0001 per share as of the grant date. Receipt of the valuation of the appraisal reporting a higher value at approximately the date of the grant resulted in a stock compensation charge for accounting purposes.

Valuation of derivative liabilities — conversion feature

We issued convertible promissory notes that each contained a conversion feature meeting the accounting definition of a derivative instrument as the feature was not clearly and closely related to the economic characteristics and risks of the convertible promissory notes. This is because the conversion feature provided for (i) conversion of the notes at a discount to the price obtained by the company for shares sold in a “Qualified Financing” (as defined) that would trigger the required conversion of the notes as well as (ii) a

"cap" on the conversion price notwithstanding the discount. We classified this feature of the notes as derivative liabilities, which were initially recorded at their fair value upon issuance of the convertible promissory notes and were subsequently remeasured to fair value at each reporting date, with changes in fair value recognized in our statement of operations.

In connection with the sale of our common stock in our initial public offering, all of the outstanding principal and accrued interest under the convertible promissory notes automatically converted into shares of common stock. As a result, subsequent to our initial public offering, we will no longer have derivative liabilities recorded on our balance sheet and will no longer recognize changes in fair value of the derivative liabilities in our statement of operations.

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 initial public offering, we determined that material weaknesses in our internal control over financial reporting existed during 2020 and 2021 which remain unremediated. See "Risk factors — 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."

Emerging Growth Company and Smaller Reporting Company Status

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

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

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of our initial public offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after our initial public offering if 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 has had a material impact on our business or financial condition, the number and complexity of these threats continue to increase. *See – Part II, Item 1.A. Risk Factors, "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."* We continue to take steps to mitigate these risks, including retaining outside information technology firms to assist us with our computer systems and information technologies although there is no assurance that these or other 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. As of September 30, 2021, and December 31, 2020, our cash and cash equivalents were 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.

As of September 30, 2021, and December 31, 2020, we had no debt outstanding other than our convertible promissory notes, all of which were converted into common stock in connection with the completion of our initial public offering, and are therefore not subject to interest rate risk related to 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, 2021, and the year ended December 31, 2020, 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, 2021. 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.

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, 2021, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. The Company has taken and continues to take steps to mitigate the risk of cyberattacks. The Company has implemented an email screening system to identify suspicious emails. The Company worked with a forensics computer support firm to investigate the Company's exposure and has engaged a second computer support firm that will, among other things, conduct ongoing training of Company staff regarding identifying suspicious emails and actions to take or not take even with emails that may appear legitimate. The Company has also implemented two factor authentication and is in the process of purchasing Company-owned computers for all employees. Company-owned computers can be managed by the Company's computer support firm and, if necessary, wiped clean of all data should doing so be warranted. Further, the Company now calls individuals known to Company employees at vendors who submit instructions for changed payment arrangements. 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.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q and in our other public filings before making an investment decision. Our business, prospects, financial condition, or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. If any such risks or uncertainties actually occur, our business, financial condition or operating results could differ materially from the plans, projections and other forward-looking statements included in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report and in our other public filings. The trading price of our common stock could decline due to any of these risks, and as a result, you may lose all or part of your investment.

Risks related to our financial position and need for additional capital

We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.

Investment in oncology product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We are still in the early stages of development of our product candidates. Our lead product candidate, TTX-MC138, is currently in the early stages and we expect to submit an IND for TTX-MC138 in the first half of 2022, and if permitted to proceed, to initiate a Phase 0 trial in patients with stage IV breast cancer shortly thereafter. We have no products licensed for commercial sale and have not generated any revenue from product sales or otherwise to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We finance our operations with funds obtained primarily through our initial public offering, the issuance of convertible promissory notes and from our SBIR Award.

We have incurred significant net losses in each period since inception. For the nine months ended September 30, 2021, and the year ended December 31, 2020, our net losses were $4,044,140 and $2,343,893, respectively. As of September 30, 2021, our total stockholders' equity was $23,155,120. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- conduct preclinical studies and clinical trials for our current and future product candidates;
- continue our research and development efforts and submit INDs for future product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- build infrastructure to support sales and marketing for any approved product candidates;
- scale up external manufacturing and distribution capabilities for clinical and, if approved, commercial supply of our product candidates;
- expand, maintain and attempt to protect our intellectual property portfolio;
- hire additional clinical, regulatory, scientific and other personnel; and
- operate as a public company.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in eventually commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek approval for, and market product candidates. We may never succeed in these activities and, even if we succeed in commercializing one or more of our current product candidates and any future product candidates, we may never generate revenues that are significant or large enough to achieve profitability. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on stockholders' equity (deficit).

We have never generated any revenue from product sales and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any product sales. We have no products approved for commercial sale, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including:

- initiating and completing research regarding, and preclinical and clinical development of, TTX-MC138 and any future product candidates;
- developing a sustainable and scalable manufacturing process for TTX-MC138 or our other product candidates and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- launching and commercializing TTX-MC138, our other product candidates and any future product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of TTX-MC138, our other product candidates and any future product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining, maintaining, attempting protection of, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if our current product candidates or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in the future in obtaining regulatory approvals to market TTX-MC138 or any future product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the price for the product we obtain, the ability to obtain reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for our current product candidates and any future product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate sufficient revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our product offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, scale back or discontinue some of our product candidate development programs or commercialization efforts.

The development of pharmaceutical drugs is capital intensive. We are currently advancing TTX-MC138 through preclinical development. Our current cash resources are insufficient to fund our planned operations or development plans. We may only be able to complete our proposed first-in-human, or FIH, studies in a small subset of patients and in only one tumor type. We may require additional funds to achieve even these more limited objectives which, if achieved, will still require additional funds to advance further. If we are capital constrained, we may not be able to meet our obligations. If we are unable to meet our obligations, or we experience a disruption in our cash flows, it could limit or halt our ability to continue to develop our product candidates or to even continue operations, either of which would have a material adverse effect on us.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek marketing approval for, our current or future product candidates. In addition, if we obtain marketing approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to sales, marketing, product manufacturing and distribution to the extent that such sales, marketing, product manufacturing and distribution are not the responsibility of our collaborators. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our current or future product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we expect to incur additional costs associated with operating as a public company. If we are unable to raise capital when needed, we would be forced to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

We expect that our existing cash and cash equivalents will be sufficient to fund our operations through December 2022. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our current or future product candidates;
- the potential additional expenses attributable to adjusting our development plans (including any supply-related matters) to the COVID-19 pandemic;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our current or future product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain;
- the extent to which we are obligated to reimburse, or are entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other current or future product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our current or future product candidates.

Identifying potential current or future product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve drug sales. In addition, our current or future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to continue to rely on additional funding to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current or future product candidates. Disruptions in the financial markets in general, and more recently due to the COVID-19 pandemic, have made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms favorable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or current or future product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly delay, scale back or discontinue one or more of our research or development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

The amount of our future losses is uncertain, and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;

- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- general market conditions or extraordinary external events, such as a recession or the COVID-19 pandemic;
- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even if we meet any previously publicly-stated guidance we may have provided.

Our independent public accounting firm previously expressed substantial doubt about our ability to continue as a going concern.

Our recurring losses from operations and negative cash flow raise substantial doubt about our ability to continue as a going concern without sufficient capital resources. As a result, prior to our initial public offering, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the years ended December 31, 2020 and 2019, with respect to this uncertainty. Our ability to continue as a going concern is dependent on both our available cash and how well we manage that cash and our operating requirements. We believe that our existing cash will be sufficient to fund our current operating plans through December 2022. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect and need to raise additional funds sooner than we anticipate. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our research and development programs and commercialization efforts.

Risks related to research and development and the biopharmaceutical industry

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a preclinical-stage oncology company with a limited operating history. We commenced operations in 2016, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting limited discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and preparing for clinical trials, and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials. Our lead product candidate, TTX-MC138, is currently in the early stages of development. We have not yet demonstrated our ability to successfully conduct or complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Investment in oncology product development a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable.

We are unable to predict the full range of risks that may emerge, and we cannot guarantee that we will meet or achieve the clinical or commercial results we expect. The future of our business depends on us successfully developing, obtaining marketing approval for, and marketing profitably our product candidates. This requires many complex scientific activities, successful pursuit of regulatory approvals, appropriate market assessments, the strategic management of intellectual property and financial resources and effective management of many other aspects of our business. Products for which we receive regulatory approval must demonstrate safety and efficacy. Competitively, the products must improve patient outcomes, deliver benefits to intended customers, maintain an affordable

price, and be superior to competitive products. To be successful, we must also be effective in driving awareness of our therapeutics to achieve market adoption for our approved products and to be profitable. The risks of missteps, setbacks, errors and failings with respect to any aspect of managing our business are an inherent part of attempted innovation in the life sciences industry. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may materially and adversely affect our business.

In addition, as an early-stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Because our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenues.

Our product candidates are development-stage technologies which require more, complex future development as well as regulatory approval prior to commercialization. It is impossible to fully mitigate the risks associated with bringing forward new technology and developing product candidates. These product candidates may fail at any point in development or in clinical trials. Therefore, there is no assurance that any of our product candidates will be successfully developed, be approved or cleared for sale by regulators, be accepted in the market or be profitable. Any delay or setback in the development of a product-candidate could materially adversely affect us.

We may not be successful in our efforts to identify or discover additional product candidates or we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

In addition to development risks, we also face the risk that existing or evolving drug regulations may create barriers to licensure that we are unable to overcome, making it impossible for us to license any product we develop. Our product candidates may fail in clinical trials. We may never achieve the product claims necessary to successfully launch any products commercially.

We may not succeed in changing the practice of medicine such that our products are adopted as we anticipate. The data we generate in our clinical programs may not be viewed by physicians as strong enough for them to use and by third-party payers as effective enough for them to reimburse the cost of our products. Further, changes in the practice of medicine may render our approved products obsolete.

We also face the risk of:

- competitors introducing technologies which render our development efforts or approved products obsolete;
- data from our clinical trials not being strong enough to support product approval or the marketing claims needed for market success and to achieve our financial projections; and
- being unable to manufacture or supply, or have manufactured or supplied on our behalf, approved products cost-effectively.

Our business is highly dependent on the success of TTX-MC138, our lead candidate which is at the early stages of development. All of our product candidates may require significant additional preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are very early in our development efforts, and only one of our product candidates, TTX-MC138, is in preclinical development and has yet to be tested in humans. If we are unable to successfully develop, obtain regulatory approval for and commercialize TTX-MC138, or experience significant delays in doing so, our business will be materially harmed. Advancing TTX-MC138 will require substantial

investment before we can seek regulatory approval and potentially launch commercial sales. Further development of TTX-MC138 will require production scaleup, clinical studies, regulatory review and approval in the U.S. and in other jurisdictions, development of sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales, if approved.

In developing TTX-MC138, among other risks, we may not be successful in synthesizing or producing the components of our proprietary formulation, or there may be toxicology issues from key components of our formulation that we have not anticipated. We have not tested TTX-MC138 using the current synthesis protocol, production processes, equipment and materials in larger quantities that would be necessary to meet clinical trial treatment demands for all anticipated patients.

We may experience setbacks that could delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- negative or inconclusive results from our preclinical studies or clinical trials or positive results from the clinical trials of others for competing product candidates similar to ours leading to their approval, and evolving to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by patients or subjects in our clinical trials or by individuals using drugs or therapeutics that we, the FDA, other regulators or others view as relevant to the development of our product candidates;
- delays in submitting IND applications or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials, including our clinical endpoints;
- delays in enrolling subjects in clinical trials, including due to the COVID-19 pandemic;
- high drop-out rates of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- poor efficacy of our product candidates during clinical trials;
- trial results taking longer than anticipated;
- trials being subjected to fraud or data capture failure or other technical mishaps leading to the invalidation of our trials in whole or in part;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays related to the impact of the spread of the COVID-19 pandemic, including the impact of COVID-19 on the FDA’s ability to continue its normal operations;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical development generally or with respect to our technology in particular; or

- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator.

Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome, and the results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or clinical trials. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology and biopharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as therapeutic products, and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of TTX-MC138 or any of our other product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- failure to receive the necessary regulatory approvals;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make a product candidate uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized.

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.

Additionally, we expect that some of our trials will be open-label studies, where both the patient and investigator know whether the patient is receiving the investigational product candidate as a monotherapy or in combination with an existing approved drug. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label trials will not be replicated in later placebo-controlled trials.

In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating our product candidates require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Although we are initially focusing our efforts on development of small-molecule drug products, we may in the future pursue development of biological products, which could make us subject to additional regulatory requirements. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. We cannot predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop.

We may seek to conduct clinical trials in foreign countries, as well as in the United States. If we continue to seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval from foreign regulatory agencies may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business.

Due to our limited resources and access to capital, we must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business.

We have limited financial and human resources and intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. In addition, we may seek to accelerate our development timelines, including by initiating certain clinical trials of our product candidates before earlier-stage studies have been completed. This approach may cause us to commit significant resources to prepare for and conduct later-stage trials for one or more product candidates that subsequently fail earlier-stage clinical testing. Therefore, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities or expend resources on product candidates that are not viable.

There can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of TTX-MC138 or any of our other product candidates in development.

Clinical trials are required to apply for regulatory approval to market TTX-MC138 or any of our other product candidates. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. We do not know whether any clinical trials we begin will continue as planned, will need to be restructured or will be completed on schedule or at all. Significant clinical trial delays also could allow competitors to bring products to market before we do and could impair our ability to successfully commercialize our product candidates, any of which could materially harm our business. CROs have recently indicated that conduct of certain preclinical animal studies to support IND filings could not begin for approximately six to eight months from the signing of contracts.

We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent our ability to receive marketing approval for, or to commercialize, TTX-MC138 or any of our other product candidates in development, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- due to the impact of the COVID-19 pandemic, we have experienced delays in our preclinical development, including access to our lab and access to our animal facility, and may continue to experience delays and interruptions to our preclinical studies and clinical trials, we may experience delays or interruptions to our manufacturing supply chain, or we could suffer delays in reaching, or we may fail to reach, agreement on acceptable terms with third-party service providers on whom we rely;
- delays and interruptions to our clinical trials could extend the duration of the trials and increase the overall costs to finish the trials as our fixed costs are not substantially reduced during delays;
- we may elect to, or regulators, IRBs, Data Safety Monitoring Boards, or DSMBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

Our product development costs will increase if we experience delays in clinical testing or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If we do not achieve our product development goals in the time frames we announce and expect, the approval and commercialization of our product candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, various aspects of the development program, such as manufacturing methods and the product's formulation, may be altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. These changes carry the risk that they will not achieve their intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

In addition, there are risks associated with process development and large-scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with current good manufacturing practice, or cGMP, requirements, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that our third-party manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our contract manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics;
- our inability to design and develop a suitable manufacturing process; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability once we begin testing TTX-MC138 and any of our other product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense of these claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;

- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- fines, injunctions or criminal penalties;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate, if approved; and
- decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We will need to obtain insurance for clinical trials as TTX-MC138, and any of our other product candidates begin clinical development. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks related to our business and industry

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biotechnology and biopharmaceutical industries continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, product candidates or products. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Quality problems could delay or prevent delivery of our products to the market.

Quality is important due to (i) the serious and costly consequences of process or product failure and (ii) it being one required element of the regulatory approval process. Receiving quality certifications is critical to the development and marketing success of our technologies. If we fail to meet existing or future quality standards, development or commercialization of our technologies could be materially and adversely affected.

We are required to comply with the FDA Quality Systems Regulations to manufacture devices, including in vitro diagnostics, anywhere in the world for sale in the United States.

Also, the International Standards Organization, or ISO, sets quality standards for medical devices, including diagnostics, that are widely accepted and applied around the world, including in the U.S. We are also subject to ISO 13485 and ISO 9000 standards. ISO 13485 is the most commonly applied standard whereby medical products companies demonstrate that their products meet quality system requirements established for Europe, Canada, Japan, Australia and other countries. The requirements of ISO 13485 cover process control, design control, retention of records, accountability, traceability, customer feedback, and other areas. We will be required to be certified under ISO 13485 to sell any approved device in Europe and other international markets. Implementing ISO 13485 is voluntary for manufacturers selling in the United States.

We will need to implement a quality system designed to meet the requirement to sell our diagnostics, if approved, in both the U.S. and Europe. We cannot guarantee that our development standards, processes and procedures will meet applicable requirements for regulatory approval in any jurisdiction or that they will mitigate all of the risks associated with the development and commercialization of our product-candidates. Even if we receive quality certifications, we could subsequently lose them or be required to take corrective actions if we do not continue to meet, implement and follow the requirements under the applicable standards. If we fail to meet quality requirements applicable to our diagnostic product-candidates and approved products, if any, it could have a material adverse effect on us.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The number of qualified clinical trial investigators and sites is limited. We expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use. This could reduce the number of patients available for our clinical trials at such clinical trial site. Clinical trials of other companies may be in similar therapeutic areas as ours. This competition will reduce the number and types of patients and qualified clinical investigators available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a competitor or clinical trial sites may not allow us to conduct our clinical trial at such site if competing trials are already being conducted there.

We may also encounter difficulties finding a clinical trial site at which to conduct our trials. Because our therapeutics represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as checkpoint inhibitors, chemotherapy, radiation and monoclonal antibodies, rather than enroll patients in any of our clinical trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our therapeutic or any other future versions of it.

Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, potency, purity and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.

Since the number of patients that we plan to dose in our planned Phase 0 and Phase 1 clinical trials of TTX-MC138 is relatively small, the results from such clinical trials, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates.

Our product candidates may cause undesirable side effects or death or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Undesirable side effects or death caused by any of our product candidates could cause us, IRBs, our CROs, the FDA or other regulatory authorities to interrupt, delay or discontinue clinical trials and could result in the denial of regulatory approval for our product candidates. This, in turn, could prevent us from commercializing our product candidates and generating revenues from their sale.

Also, any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from becoming profitable.

Sales of our products may involve a lengthy sales cycle.

Many factors are expected to influence the sales cycle for our approved products. These factors include the future state of the market, the perceived value of our product candidates, the evolution of competing technologies, insurance coverage or prior authorization requirements and changes in medical practices. Any of these may adversely affect our sales cycles and the rate of market acceptance of our approved products.

Risks related to regulatory approval, healthcare regulations and ongoing regulatory compliance

We are very early in our development efforts. All of our product candidates are still in preclinical development. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We have very limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA, and, as a company, we have no experience in obtaining approval of any product-candidate. The time required to obtain FDA and other approvals is unpredictable but typically takes one or more years following completion of clinical trials, depending upon the type, complexity and novelty of the product-candidate. We may encounter delays or rejections during any stage of the regulatory review and approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of a product-candidate to meet, FDA requirements for safety, efficacy and quality.

The standards that the FDA and its foreign counterparts use when regulating us are not always applied predictably or uniformly and can change. Because the drugs we are developing may represent a new class of drug, the FDA and its foreign counterparts have not yet established any definitive policies, practices or guidelines in relation to these drugs. The lack of policies, practices or guidelines may hinder or slow review by the FDA of regulatory filings that we may submit. Moreover, the FDA may respond to these submissions by defining requirements we may not have anticipated. Such responses could lead to significant delays in and added costs for the clinical development of our product candidates.

Any analysis of data from preclinical and clinical activities that we perform is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

In addition, the FDA may delay, limit, or deny approval of a product-candidate for many reasons, including:

- disagreement with the design or implementation of clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product-candidate is safe and effective for any indication;
- we may be unable to demonstrate that a product-candidate’s clinical and other benefits outweigh its safety risks;

- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the results of our clinical trials may not demonstrate the safety or efficacy required by the FDA for approval; or
- the FDA may find deficiencies in our manufacturing processes or facilities; and the FDA's approval policies or regulations may significantly change in a manner rendering our clinical data insufficient for approval.

After submission of an NDA, the FDA may refuse to review the application, deny approval of the application, require additional testing or data or, if the NDA is filed and later approved, require post-marketing testing and surveillance to monitor the safety or efficacy of a product. Under the Prescription Drug User Fee Act, or PDUFA, the FDA has agreed to certain performance goals in the review of NDAs. The FDA's timelines are flexible and subject to change based on workload and other potential review issues which may delay FDA's review of an NDA. For example, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals. However, FDA may not be able to continue its current pace and review timelines could be extended. Further, the terms of approval of any NDA, including the product labeling, may be more restrictive than we desire which could affect the marketability of our products.

Even if we comply with all FDA regulatory requirements, we may not obtain regulatory approval for any of our product-candidates. If we fail to obtain regulatory approval for any of our product-candidates, we will have no commercialized products for sale and therefore have no ability to general significant, if any, revenue.

Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy, or REMS, plan as part of or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

If we or any collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. Enforcement actions can include, among others:

- adverse regulatory inspection findings;
- warning letters;
- voluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals;
- restrictions on, or prohibitions against, marketing our products;
- restrictions on, or prohibitions against, importation or exportation of our products;
- suspension of review or refusal to approve pending applications or supplements to approved applications;

- exclusion from participation in government-funded healthcare programs;
- exclusion from eligibility for the award of government contracts for our products;
- suspension or withdrawal of product approvals;
- product seizures;
- injunctions; and
- civil and criminal penalties and fines.

In addition, if any of our products cause serious or unexpected side effects or are associated with other safety risks after receiving marketing approval, a number of potential significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall the product, change the way it is administered, conduct additional clinical trials or change the labeling of the product;
- the product may be rendered less competitive and sales may decrease;
- litigation or class action lawsuits;
- our reputation may suffer generally both among clinicians and patients; or
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use or impose restrictions on distribution in the form of a REMS in connection with approval, if any.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that our products are unlikely to receive regulatory approval or unlikely to be successfully commercialized.

A variety of factors, including inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, accept payments of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result of these and other factors. In particular, it has been reported that FDA's planned expansion of its oncology division is delayed. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. As of May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, remain temporarily postponed. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021 announced plans to continue progress toward resuming standard operational levels. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel or for other reasons, and the FDA does not determine a remote interactive evaluation would be adequate, the agency has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Even if we receive regulatory approval of TTX-MC138 or any of our other product candidates, we will be subject to ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for TTX-MC138 or another product-candidate may require post-marketing surveillance to monitor the safety and efficacy of the product and may require us to conduct post-approval clinical studies. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements can include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval and applicable product tracking and tracing requirements. Compliance with ongoing and changing requirements takes substantial resources and, should we be unable to remain in compliance, our business could be materially and adversely affected.

In addition, if we pursue, and ultimately obtain, accelerated approval of TTX-MC138 based on a surrogate endpoint, the FDA would require us to conduct a confirmatory trial to verify the predicted clinical benefit as well as additional safety studies. The results from the confirmatory trial may not support the clinical benefit, which would result in the approval being withdrawn.

Manufacturers and their facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- consent decrees or injunctions or the imposition of civil or criminal penalties.

Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is not inconsistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any drugs on the market, if we begin commercializing our current or future product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any current or future product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our current or future product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other hand. The term remuneration has been interpreted broadly to include anything of value. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistle-blower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties. Government enforcement agencies and private whistle-blowers have investigated pharmaceutical companies for or asserted liability under the False Claims Act for a variety of alleged promotional and marketing activities, such as providing free products to customers with the expectation that the customers would bill federal programs for the products; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for "off-label" uses; and submitting inflated best price information to the Medicaid Rebate Program. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the ACA require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Department of Health and Human Services information related to physician payments and other transfers of value and the ownership and investment interests of such physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Obtaining and maintaining regulatory approval for our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that or of any of our other product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval for our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval for TTX-MC138, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product-candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as preclinical studies and clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product-candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we charge for our product is also subject to regulatory approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, changes to our manufacturing arrangements; additions or modifications to product labeling; the recall or discontinuation of our products; or additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and likely will continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biotechnology and biopharmaceutical industries. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts from the negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. In addition, the Trump administration has issued various Executive Orders, which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. On December 20, 2019, President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, or BBA, will remain in effect through 2030, unless additional congressional action is taken. However, these Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. The BBA also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more

transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

At the federal level, the Trump administration's budget for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. The Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule that would allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On July 24, 2020, President Trump signed four Executive Orders aimed at lowering drug prices. The Executive Orders direct the Secretary of HHS to: (1) eliminate protection under an AKS safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re-importation of insulin products, and prioritize finalization of the proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) require Federally Qualified Health Centers, or FQHCs, participating in the 340B drug program to provide insulin and injectable epinephrine to certain low-income individuals at the discounted price paid by the FQHC, plus a minimal administrative fee. On October 1, 2020, the FDA issued the final rule allowing importation of certain prescription drugs from Canada. On August 6, 2020, President Trump signed an additional Executive Order directing U.S. government agencies to encourage the domestic procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs, which include among other things, active pharmaceutical ingredients and drugs intended for use in the diagnosis, cure, mitigation, treatment, or prevention of COVID-19. The FDA has been directed to release a full list of Essential Medicines, Medical Countermeasures, and Critical Inputs affected by this Order by November 5, 2020. On September 13, 2020, President Trump signed an Executive Order directing HHS to implement a rulemaking plan to test a payment model, pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita gross domestic product. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

Additionally, on July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and identify and address any efforts to impede generic drug competition.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals, and we could be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Healthcare reform in the U.S. and other countries may materially and adversely affect us.

In the U.S. and in many foreign jurisdictions, the legislative landscape continues to evolve. Our revenue prospects could be affected by changes in healthcare spending and policies in our target markets. We operate in a highly regulated industry and new laws or judicial decisions, or new interpretations of existing laws or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could materially and adversely affect us.

There is significant interest in promoting healthcare reform, as evidenced by the enactment in the U.S. of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act in 2010, or together, the ACA. It is likely that many governments will continue to consider new healthcare legislation or changes to existing legislation. We cannot predict the initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified, or how they may affect us. The continuing efforts of governments, insurance companies, managed care organizations and other third-party payors to contain or reduce healthcare costs may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

Under the ACA, there are many programs and requirements for which details or consequences are still not fully understood. We are unable to predict what healthcare programs and regulations will ultimately be implemented at any level of government in or outside the U.S., but any changes that decrease reimbursement for our approved products, reduce volumes of medical procedures or impose new cost-containment measures could adversely affect us.

We are subject to geopolitical risks, economic volatility, anti-corruption laws, export and import restrictions, local regulatory authorities and the laws and medical practices in foreign jurisdictions.

The costs of healthcare internationally have risen significantly over the past decade. Numerous initiatives and reform by legislators, regulators and third-party payers to curb these costs have reduced reimbursement rates. One outcome of these dynamics is that hospitals and others are consolidating into larger integrated delivery networks and group purchasing organizations in an effort to reduce administrative costs and increase purchasing power. This consolidation has resulted in greater pricing pressure on suppliers, decreased average selling prices and changes in medical practices. If we secure marketing approval for our product candidates, our commercial success will be determined by, among other things, our ability to obtain acceptable pricing for approved products which will be subject to, among other things, the factors described above.

The expansion of group purchasing organizations, integrated delivery networks and large single accounts among hospitals could also put price pressure on our approved products. We expect that market demand, government regulation, third-party reimbursement policies, government contracting requirements and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and competitors. The result may be further downward pressure on the prices we are able to obtain, thus adversely affecting us.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

Risks related to commercialization

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell any products for which we obtain regulatory approval, we may not be able to generate product revenue.

We have no sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we expect to establish a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop and for which we receive regulatory approval ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

In the United States and in other countries, patients who are prescribed treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory marketing approval will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Government authorities and other third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health care programs and private health insurers. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug and biologic benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs and biologics. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs and biologics, and each drug plan can develop its own formulary that identifies which drugs and biologics it will cover, and at what tier or level. However, Part D prescription drug formularies must include products within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs and biologics in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs and biologics may increase demand for products for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug or biologic product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer price, or AMP, and Medicaid rebate amounts reported by the manufacturer. As of 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As the required 340B discount is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. The Centers for Medicare & Medicaid Services, or CMS, has previously and may in the future implement reductions in Medicare Part B reimbursement for 340B drugs through notice and comment rulemaking. It is unclear how such reimbursement reductions could affect covered hospitals who might purchase our products in the future, and affect the rates we may charge such facilities for our approved products.

Changes to these current laws and state and federal healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new oncology drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major biotechnology and biopharmaceutical companies, specialty biotechnology and biopharmaceutical companies, and other biotechnology and biopharmaceutical companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Not only must we compete with other companies that are focused on therapeutics that treat cancer, but also any product candidates that we successfully develop and commercialize will compete with existing and new therapies that may become available in the future. Our competitors may develop more successful products similar to ours sooner than we can commercialize ours, which may negatively impact our results. Companies that we are aware of with targeted therapeutics in the treatment of various cancers include Nurix Therapeutics, Black Diamond Therapeutics and Precision Biosciences, which have product candidates in various stages of preclinical and clinical developments. Other companies focusing on RNA therapeutics include Arrowhead Pharmaceuticals, a clinical stage company, with a pipeline of investigational RNAi therapeutics focused on genetic medicines, cardio-metabolic diseases, hepatic infectious diseases, oncology and central nervous system/ocular diseases. However, we know of no other companies currently in clinical development with miRNA therapeutics targeting metastatic disease. For additional information regarding our competition, see “Business — Competition.”

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do.

Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient, or less expensive than any products that we may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments of the biological processes that drive cancers as well, which could give such products significant regulatory and market timing advantages over TTX-MC138 or other product candidates that we may identify. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors. The availability of competitive products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

If, in the future, we are unable to establish sales and marketing and patient support capabilities or enter into agreements with third parties to sell and market our current or future product candidates, we may not be successful in commercializing our current or future product candidates if and when they are approved, and we may not be able to generate any revenue.

We do not currently have a sales or marketing infrastructure and have no experience in the sales, marketing, patient support or distribution of drugs. We currently intend to partner with a larger commercial organization to market any of our product candidates, if approved, though our intentions may change in the future. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, patient support, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our current or future product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing and patient support capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our current or future product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs, if approved;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing, patient support and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any current or future product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our current or future product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our current or future product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our current or future product candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

Risks related to third parties and suppliers

We expect to rely on third-party manufacturing and supply vendors, and our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of TTX-MC138 and any future potential product candidates that we may develop. There can be no assurance that our preclinical and clinical development product supplies will not be limited or interrupted, or that they will be of satisfactory quality or continue to be available at acceptable prices. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our product candidates will depend on the severity and duration of the spread of the virus and the actions undertaken to contain COVID-19 or treat its effects. Three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and more may be authorized in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials,

which could lead to delays in these trials. Any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

We may be unable to establish additional agreements, or extend existing agreements, with third-party manufacturers or to do so on terms acceptable to us. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third-party for sufficient quantity and quality at acceptable costs which could delay, prevent or impair our development or commercialization efforts;
- the possible breach of the manufacturing agreement by the third-party;
- failure to meet our manufacturing specifications;
- failure to meet our manufacturing schedule;
- misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us;
- disruptions to the operations of our manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of a manufacturer or supplier; and
- reliance on the third-party for regulatory compliance, quality assurance and safety reporting.

Our reliance on others for our manufacturing will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all applicable regulations regarding manufacturing. Our product candidates and any products that we may develop may compete for access to manufacturing facilities with other product candidates and products. There are a limited number of manufacturers that operate in accordance with cGMP regulations that might be capable of manufacturing for us which could restrict our ability to supply products and, as a result, have a material adverse effect on us.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or could otherwise adversely affect our ability to commercialize our approved products. Some of these events could be the basis for costly FDA action, including injunction, recall, seizure or total or partial suspension of production.

We will have limited control over the day-to-day manufacturing and quality operations of our contract manufacturers. While we will exercise commercially reasonable efforts to oversee operations and embed our quality system standards and controls in our manufacturing agreements, we will remain subject to the performance of our contract manufacturers. We must depend on our suppliers for proper oversight and control of their operations. Our outside manufacturers may themselves rely on other parties that they do not control. Our suppliers might fail to obtain, or experience delays in obtaining, regulatory approvals applicable to the aspects of their business that pertains to us. As a result, the development and commercialization of our products may be delayed. If this occurs, we may need to identify alternative sources of supply which may not be feasible, or which may adversely affect our timelines and financial results.

Our dependence upon others for the manufacture of our product candidates or products may adversely affect our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Thus, our current and anticipated future dependence upon others for manufacturing may adversely affect our timelines, our future profit margins or our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We depend, or may depend in the future, upon third parties to conduct certain aspects of our preclinical studies and clinical trials, under agreements with universities, medical institutions, CROs, strategic collaborators and others. We expect to have to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs.

We will rely especially heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons or if, due to federal or state orders or absenteeism due to the COVID-19 pandemic, they are unable to meet their contractual and regulatory obligations, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Parties conducting some or all of our product manufacturing may not perform satisfactorily.

Outside manufacturers may not be able to or may not comply with cGMP regulations or similar regulatory requirements outside the U.S. Our failure, or the failure of our manufacturers, to comply with applicable regulations could delay clinical development or marketing approval or result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays,

suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

We may not have arrangements for redundant supply or a second source for key materials, components or our products and product candidates. If our contract manufacturers cannot perform as expected, we may be required to replace such manufacturers. There may be only a small number of potential alternative manufacturers who could manufacture our product candidates. We may incur added costs and delays in identifying, gaining access to and qualifying any such replacement.

We are highly dependent on others to provide services for certain core aspects of our business.

To conserve financial resources, we utilize consultants, advisors and other parties for certain functions including regulatory affairs, clinical trials, medical practice issues, product management and human resources. If other parties are not available to provide services through completion of our programs at the time we require their services, or if the expertise we require is not readily available, the development and commercialization of our product candidates may be delayed.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products.

A part of our strategy is to seek, evaluate and, when strategically attractive, enter into development and commercial partnerships. Potential partners may include larger medical products companies. These potential partners often have their own internal development programs and priorities which may be a potential source of competition for our product candidates. We must develop technologies of value and then demonstrate the value of our technologies and product candidates if we are to be successful in arranging strategic partnerships on terms that will be attractive. There are no assurances that we will succeed in arranging any partnerships.

Identifying appropriate partners for our product candidates and the negotiation process is lengthy, time-consuming and complex and we have limited resources to do this. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically and technologically valuable with features or benefits that are superior to existing products or product candidates in development. We may not be able to maintain such strategic partnerships if, for example, development or approval of a product is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our product candidates could delay their development and commercialization and reduce their competitiveness even if they reach the market.

In addition, strategic partners may not perform as we expect or may breach their agreements with us. We may not be able to adequately protect our rights under these agreements and attempting to do so is likely to be time consuming and expensive. Furthermore, our strategic partners will likely seek to control certain decisions regarding the development and commercialization of our product candidates and may not conduct those activities in the manner or time we would like.

If we fail to establish and maintain strategic partnerships related to our product candidates, we will bear all of the risk and costs related to the development and commercialization of our product candidates. This may require us to seek additional financing, hire additional employees and otherwise develop expertise which we do not have. These factors could materially and adversely affect the development or commercial success of any product-candidate for which we do not arrange a strategic partnership.

Risks related to managing our business and operations

The global pandemic of the novel coronavirus disease, COVID-19, has, and may continue to, adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, a novel strain of coronavirus disease that causes COVID-19 was identified in Wuhan, China. As of the date of this Quarterly Report on Form 10-Q, the novel coronavirus (also called SARS-CoV-2) has spread to a number of countries globally, including the United States, and the disease outbreak was declared a pandemic by the World Health Organization in March 2020. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. While COVID-19 vaccines are now being distributed in the United States and around the world, it will take time to widely administer the vaccines and achieve herd immunity locally and globally. Further, new strains of COVID-19 have accelerated and expanded the spread of this outbreak. In response to the spread of COVID-19, we have continued operations and all employees are working from home.

In March 2021, we moved our laboratory operations to facilities leased from the Massachusetts Biomedical Initiatives, Inc., or MBI, in Worcester, Massachusetts. While we believe we will have sufficient access to the MBI facilities, there is no assurance that this will be the case. Should access to the MBI facility be limited, or should other pandemic-related restrictions be imposed, our development work would be further adversely affected. The extent of such adverse effects will depend on future developments which are highly uncertain and cannot be predicted.

As a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in commencing enrollment of patients in our clinical studies and/or clinical trials, including the Phase 0 exploratory IND study and, if permitted to proceed, our Phase 1 and Phase 2 clinical trials;
- the impact from potential delays, including potential difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures that are deemed non-essential, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;

- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and

- interruption or delays to our sourced discovery and clinical activities.

The COVID-19 pandemic continues to rapidly evolve.

The extent to which the outbreak ultimately impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2021, we had eight employees including one part-time contractor. We also utilize various outside companies and individuals under consulting or other arrangements to support our operations. As our clinical development and commercialization plans and strategies develop, and as we continue to operate as a public company, we expect we will need additional human resources in areas including management, clinical and regulatory, manufacturing, research, medical, sales, marketing, financial, and other. Future growth would impose significant added responsibilities on members of management, including:

- recruiting, integrating, retaining and motivating additional employees;

- managing our development efforts effectively, including the clinical, manufacturing and quality review process for our product candidates, while complying with our contractual obligations to contractors, collaboration partners and other third parties; and

- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on third parties, including independent organizations, advisors and consultants, to provide certain services to support and perform our operations. There can be no assurance that the services of these third parties will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other suitable outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully execute the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our development and commercialization goals.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive oncology industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are dependent on our management, scientific and medical personnel and advisors, including our co-founder and CEO, Robert Michael Dudley, our co-founder and Chief Technology Officer, Dr. Zdravka Medarova, our CFO and director, Thomas A. Fitzgerald, our chief scientist Dr. Peter Liu, our Sr. VP of Operations Dr. Judy Carmody, our co-

founder Dr. Anna Moore, our board of directors and members of our scientific and business advisory boards as well as our many consultants. The loss of the services of any of these individuals, and our inability to find suitable replacements, could result in delays in product development and materially harm our business.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

The estimates of market opportunity and forecasts of market growth included in this report or that we may otherwise provide may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Market opportunity estimates and growth forecasts included in this report or that we may otherwise provide are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. The estimates and forecasts included in this report relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet the size estimates and growth forecasts included in this report, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

We may be exposed to significant foreign exchange risk.

We incur expenses, and may in the future derive revenues, in a variety of currencies. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. To date, we have not had significant proportions of our spending tied to foreign currencies but this may change in the future. Thus, fluctuations in currency exchange rates could affect our results as expressed in U.S. dollars. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products.

The Animal Welfare Act, or AWA, is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA and comparable rules, regulations, and or obligations that may exist in many foreign jurisdictions. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and/or obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

We have net operating loss carryforwards and tax credit carryforwards for U.S. federal and state income tax purposes which begin to expire in future years. Additionally, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50 percentage points within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Private placements and other transactions that have occurred since our inception, as well as our initial public offering, may trigger such an ownership change pursuant to Section 382. Any such limitation, whether as the result of our initial public offering, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years.

The reduction of the corporate tax rate under the Tax Cuts and Jobs Act of 2017, or the Tax Cuts and Jobs Act, may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Our ability to utilize those net operating loss carryforwards could be limited by an “ownership change” as described above, which could result in increased tax liability to us.

Risks related to our intellectual property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our business will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patenting process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied. In addition, we may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biotechnology and biopharmaceutical fields involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our technology, including our product candidates, or prevent others from designing around the claims in our patents. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We cannot be certain that we were the first to file any patent application related to our technology, including our product candidates, and, if we were not, we may be precluded from obtaining patent protection for our technology, including our product candidates.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for United States applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor's disclosure.

We may be required to disclaim part or all of the term of certain patents. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect our product candidates, or would be found by a court to be infringed by a competitor's technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products that have the same effect as our products on an independent basis and that do not infringe our patents or other intellectual property rights, or will design around the claims of patents that may issue that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy-Smith America Invents Act, or the America Invents Act, after March 2013, the United States moved from a "first-to-invent" to a "first-inventor-to-file" system. Under a "first-inventor-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear, as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-inventor-to-file" provisions. In addition, the courts have yet to address many of these provisions and the applicability of the America Invents Act and new regulations on specific patents discussed herein, for which issues have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents or those of our licensors;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications invented or developed using U.S. government funding, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;

- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

The patents covering our lead candidate, TTX-MC138, are currently issued only in the U.S. and there are no foreign applications pending for this invention at this time. We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to oncology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Third-party claims of intellectual property infringement may be costly and time consuming to defend, and could prevent or delay our product discovery, development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management’s attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party’s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner’s attorneys’ fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our product candidates and any license that is available may be non-exclusive, which could result in our competitors gaining access to the same intellectual property; and
- the need to redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

If we are not able to obtain and enforce patent and other intellectual property protection for our technologies, development and commercialization of our product candidates may be adversely affected and our business materially harmed.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licensing intellectual property rights of others, for our product candidates, methods used to manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing our proprietary rights and to operate without infringing the proprietary rights of others.

We and our current or future licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our technologies at reasonable cost, in a timely fashion, or at all. The patent position of oncology companies can be highly uncertain because it involves complex legal and factual questions. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable, or that any issued or granted patents will include claims that are sufficiently broad to cover our product candidates or delivery technologies or provide meaningful protection from our competitors. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect us.

While we will endeavor to try to protect our technologies with intellectual property rights such as patents, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the process of pursuing patent coverage. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than otherwise would have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in oncology patents. Moreover, changes in either the patent laws or in the interpretations of patent laws may diminish the value of our intellectual property. As such, we do not know the degree of future protection that we might have with respect to our proprietary technologies. Further, patents have a limited lifespan.

In the United States and in industrialized countries generally, a patent expires 20 years after it is filed (or 20 years after the filing date of the first non-provisional US patent application to which it claims priority). Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our technologies, we may be more susceptible to competition, including from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product-candidate limits the time during which we can market a product-candidate under patent protection, which may particularly and adversely affect our profitability.

Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our current or future product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

Confidentiality agreements with employees and others may not prevent unauthorized disclosure of proprietary information.

Among the ways we attempt to protect our intellectual property is by entering into confidentiality agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are intended to protect (i) proprietary know-how that may not be patentable or that we may elect not to patent, (ii) processes for which patents are difficult to enforce and (iii) other elements of our technology not covered by patents. Although we use reasonable efforts to protect our intellectual property, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our intellectual property to competitors or others. In addition, competitors may otherwise gain access to our intellectual property or independently develop substantially equivalent information and techniques. Enforcing a claim that another party illegally obtained and is using any of our intellectual property is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. sometimes are less willing than U.S. courts to protect intellectual property. Misappropriation or unauthorized disclosure of our intellectual property could materially and adversely affect our competitive position and may have a material adverse effect on us.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and biopharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest claimed U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our current or future product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a “first inventor to file” system. The first-inventor-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the U.S. and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Risks related to our common stock

The price of our common stock may be volatile or may decline regardless of our operating performance, and shareholders may not be able to resell their shares at or above the price at which they purchase those shares.

Prior to our initial public offering, there had been no public market for shares of our common stock. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. An active or liquid market in our common stock may not develop or, if it does develop, it may not sustain. As a result of these and other factors, shareholders may not be able to resell their shares of our common stock at or above the price at which they purchase those shares.

Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price is likely to be volatile. The stock market in general and the market for the stocks of biopharmaceutical companies in particular have experienced extreme price and volume fluctuations often unrelated or disproportionate to the operating performance of particular companies, including as a result of the COVID-19 pandemic. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. As a result of the foregoing, shareholders may not be able to sell their common stock at or above the price at which they purchase those shares. The market price for our common stock may be influenced by many factors, including:

- the success of competitive drugs or technologies;
- results of clinical trials of our current or future product candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our current or future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional current or future product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management’s attention and resources.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock, restrict our operations or require us to relinquish rights to our technologies or current or future product candidates.

Until such time, if ever, as we can generate the cash we need from operations, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible into or exchangeable for common stock, the ownership interest of our shareholders will be diluted, and the terms of these new securities may include liquidation or other preferences that materially adversely affect the rights of our shareholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or current or future 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, scale back or discontinue the development and commercialization of one or more of our product candidates, delay our pursuit of potential in-licenses or acquisitions, or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves.

Our executive officers, directors, principal stockholders and their affiliates exercise significant influence over our company, which will limit the ability of our other shareholders to influence corporate matters and could delay or prevent a change in corporate control.

The existing holdings of our executive officers, directors, principal stockholders and their affiliates, represent beneficial ownership, in the aggregate, of approximately 32.6% of our outstanding common stock as of November 12, 2021. The foregoing calculation excludes the possible exercise of options. If the specified individuals exercised all options they hold, and no other options were exercised by any other holder, the specified individuals would represent beneficial ownership, in the aggregate, of approximately 39.0% of our outstanding common stock. As a result of their combined ownership, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation or sale of all or substantially all of our assets. These stockholders acquired their shares of common stock for substantially less than the price of the shares of common stock sold in our initial public offering, and these stockholders may have interests, with respect to their common stock, that are different from those of investors in our initial public offering or who invest in our shares subsequent to our initial public offering, and the concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and

- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, or DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, or EGC, as defined in the JOBS Act, enacted in April 2012. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an EGC for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an EGC until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

We do not intend to pay cash dividends on our common stock, so any returns will be limited to the value of our stock.

We currently anticipate that we will retain any future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying cash dividends for the foreseeable future. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of the value of their stock, if any, and which could decrease in value resulting in losses to our stockholders.

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.

As a public company, we will be required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

To date, we have had limited financial and accounting personnel to fully execute our accounting processes and address our internal control over financial reporting. During 2021, in connection with the preparation of our financial statements as of and for the years ended December 31, 2020 and 2019, we identified material weaknesses in our control over financial reporting.

We did not design and therefore did not have an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient number of professionals with segregated duties with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately.

While these material weaknesses did not result in a misstatement for the years ended December 31, 2020 and 2019, each of the above material weaknesses could have resulted in a misstatement of the aforementioned account balances or disclosures that could have resulted in a material misstatement to the annual or interim financial statements that would not have been prevented or detected.

In order to remediate the material weaknesses in our internal control over financial reporting and address the material weaknesses in our accounting processes, we plan to establish more robust accounting policies and procedures, review the adoption of new accounting positions and the need for financial statement disclosures, and engage consultants to assist us in determining what personnel are needed and in evaluating new accounting policies.

We began implementing and plan to continue to implement steps to address the internal control deficiencies that contributed to the material weaknesses, including the following:

- hiring of additional finance and accounting personnel with requisite experience and technical accounting expertise, supplemented by third-party resources;
- documenting and formally assessing our accounting and financial reporting policies and procedures; and
- assessing significant accounting transactions and other technical accounting and financial reporting issues, preparing accounting memoranda addressing these issues and maintaining these memoranda in our corporate records.

While we believe that these efforts will improve our internal control over financial reporting, the implementation of these measures will be ongoing and will require validation and testing of the design and operating effectiveness of our internal controls over a sustained period of financial reporting cycles. We cannot reasonably estimate when these remediation measures will be completed nor can we assure you that the measures we have taken to date, and are continuing to take, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal controls over financial reporting. Furthermore, we may not have identified all material weaknesses, and our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Accordingly, there continues to be a reasonable possibility that these deficiencies or others could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis.

If we continue to fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an EGC, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

Our amended and restated bylaws designate a certain court as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or by-laws or (v) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternate forum, the United Stated District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, as our principal office is located in Boston, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in our shares of common stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general additional litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. In addition, these forum selection clauses in our bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Moreover, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware may also reach different judgments

or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

We may not be able to continue to meet the listing requirements of the Nasdaq Capital Market or maintain a listing of our common stock on the Nasdaq Capital Market.

Since our common stock is listed on the Nasdaq Capital Market, we must meet certain financial and liquidity criteria to maintain such listing. If we violate the Nasdaq Capital Market listing requirements, our common stock may be delisted. If we fail to meet any of the Nasdaq Capital's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from the Nasdaq Capital Market may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of our stockholders' investment.

General Risk Factors

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our current or future product candidates' development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our current or future product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or current or future product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our current or future product candidates could be delayed.

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.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the European Union, or EU, General Data Protection Regulation, or GDPR) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Like many other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems and attempts to damage or steal our property, information or financial resources, including through malicious codes and viruses, phishing, business email compromise attacks, and attempted ransomware or other cyber-attacks. Whereas none of these instances has had a material impact on us so far, the number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our third party service providers occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. Such a material breach could also have a material adverse effect on our business, financial condition or results of operations.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from any such serious disaster.

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event were to occur that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U.S. and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, patient support and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes

numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including periods of severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, including most recently in connection with the outbreak of the novel coronavirus.There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any debt or equity financing we seek to obtain more difficult, more costly, and more dilutive.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Furthermore, our stock price may decline due in part to the volatility of the stock market and general economic conditions.

We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials.

Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may (i) create uncertainty in our business, (ii) affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, (iii) result in liability or (iv) impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort, or proceedings against us by governmental entities or others. Recently, California passed the California Data Privacy Protection Act of 2018, or the CCPA, which went into effect in January 2020. The CCPA provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as for private rights of action for data breaches that is expected to increased at a breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. The CCPA may lead to similar laws in other U.S. states or at a national level, which could increase our potential liability and adversely affect our business.

In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, if we establish operations or conduct clinical trials in Europe, we will be subject to European data privacy laws, regulations and guidelines. The General Data Protection Regulation, (EU) 2016/679, or GDPR, became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the European Economic Area, or EEA. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to €10 million or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to €20 million or up to 4% of our total worldwide annual turnover (i.e., revenues), whichever is greater, for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers.

Further, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, possibly implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country. As a result, we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions. European laws have historically differed quite substantially in this field, leading to additional uncertainty. The U.K.'s decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the U.K. In particular, it is unclear how data transfers to and from the U.K. will be regulated now that the U.K. has left the EU.

We may conduct clinical trials in the EEA where the GDPR would increase our responsibility and liability in relation to personal data that we process when such processing is subject to the GDPR, and when we are required to have in place additional mechanisms and safeguards to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time-intensive process that would increase our cost of doing business or require us to change our business practices. Despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. We expect that we will face uncertainty as to whether our efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our business and on our ability to attract and retain new clients or biotechnology and biopharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national vendors or biotechnology and biopharmaceutical partners to use our products due to the potential risk exposure as a result of data protection obligations imposed on them by law, including the GDPR. Such vendors or biotechnology and biopharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the forgoing could materially harm our business, prospects, financial condition and results of operations.

We or any future strategic partners may become subject to third-party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights.

We or any future strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. If we, our licensors or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay substantial damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. In addition, we, our licensors or any future strategic partners may choose to seek, or be required to seek, a license to technology owned by a third-party, which license may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be limited which could give our competitors access to the same technology or intellectual property rights as is licensed to us. If we fail to obtain a required license, we may be unable to effectively market certain approved products which could materially harm us. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. In addition, we may find it necessary to pursue claims or initiate

lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in litigation or other proceedings relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and would divert our management's attention from operating the business. Most of our competitors would be better able to sustain the costs of complex patent litigation than us because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could materially delay our research and development efforts and significantly limit our ability to continue our operations.

If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that may not be covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe any patents we may own or in-license. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license do not cover the technology in question or that such third-party's activities do not infringe our patent applications or any patents we may own or in-license. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in- license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Depending upon the timing, duration and specifics of FDA marketing approval of our current or future product candidates, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Different laws govern the extension of patents on approved pharmaceutical products in Europe and other jurisdictions. However, we may not be granted a patent extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. For example, we may not be granted an extension in the U.S. if all of our patents covering an approved product expire more than fourteen years from the date of NDA approval for a product covered by those patents. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

Post-grant proceedings provoked by third-parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license. These proceedings are expensive, and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO post-grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post-grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings within patent offices may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not be able to detect infringement against any patents we may own or in-license. Even if we detect infringement by a third-party of any patents we may own or in-license, we may choose not to pursue litigation against or settlement with the third-party. If we later sue such third-party for patent infringement, the third-party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third-party.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of an initial public offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, or increase our costs, they could have a material adverse effect on our business, financial condition and results of operations and may require us to reduce costs in other areas of our business or increase the prices of any products or services we may offer in the future. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to comply with these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

(a) Recent Sales of Unregistered Equity Securities

None.

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

On July 8, 2021, our Registration Statement on Form S-1, as amended (File No. 333-253599) was declared effective in connection with our initial public offering, or IPO, pursuant to which we sold 7,187,500 shares of our common stock, including the full exercise of the underwriters’ option to purchase additional shares, at a price to the public of $4.00 per share. The closing of our initial public offering occurred on July 13, 2021. We received net proceeds from the initial public offering of approximately $25.4 million (after deducting underwriters’ discounts and commissions and additional offering related costs).

No expenses incurred by us in connection with our initial public offering were paid directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

There has been no material change in the planned use of proceeds from our initial public offering from those disclosed in the final prospectus for our initial public offering dated as of June 8, 2021, and filed with the SEC on July 9, 2021, pursuant to Rule 424(b)(4).

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

ITEM 6. EXHIBITS

3.2	Amended and Restated Certificate of Incorporation of TransCode Therapeutics, Inc. (Incorporated by reference to Exhibit 3.3 to the Registrant's Registration Statement on Form S-1, filed on February 26, 2021 (File No. 333-253599)).
3.3	Amended and Restated Bylaws of TransCode Therapeutics, Inc. (Incorporated by reference to Exhibit 3.5 to the Registrant's Registration Statement on Form S-1, filed on February 26, 2021 (File No. 333-253599)).
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	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Convertible Preferred Stock, Common Stock and Stockholders' Equity (Deficit), (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements (filed herewith)

* 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 15, 2021

/s/ R. Michael Dudley
R. Michael Dudley
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.1

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

I, Robert Michael Dudley, M.D., 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; 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 15, 2021

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; 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 15, 2021

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, 2021, 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 15, 2021

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, 2021, 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 15, 2021

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