

As filed with the U.S. Securities and Exchange Commission on August 29, 2023.

Registration No. 333-

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

TRANSCODE THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

81-1065054
(I.R.S. Employer
Identification No.)

**6 Liberty Square, #2382
Boston, MA 02109
(857) 837-3099**

(Address, including zip code and telephone number, including area code, of Registrant's principal executive offices)

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Chief Executive Officer
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information contained in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION

DATED AUGUST 29, 2023

Shares of Common Stock Up to Pre-Funded Warrants to Purchase Common Stock

T R A N S C O D E
T H E R A P E U T I C S TM

TransCode Therapeutics, Inc.

We are offering _____ shares of our common stock on a firm commitment basis.

Our common stock is listed on the Nasdaq Capital Market under the symbol “RNAZ.” The last reported sale price of our common stock on the Nasdaq Capital Market on August 28, 2023 was \$1.67 per share. The final public offering price will be determined through negotiation between us and the underwriter; the recent market price used throughout this prospectus may not be indicative of the actual offering price.

We are also offering to each purchaser whose purchase of shares of our common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the holder, 9.99%) of our outstanding shares of common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded warrants to purchase shares of common stock, or the pre-funded warrants, in lieu of shares of common stock. Each pre-funded warrant will be exercisable for one share of our common stock. The purchase price of each pre-funded warrant will equal the price per share of common stock being sold to the public in this offering, minus \$0.01, and the exercise price of each pre-funded warrant will be \$0.01 per share. For each pre-funded warrant that we sell, the number of shares of our common stock that we are offering will be decreased on a one-for-one basis. The pre-funded warrants will not be listed on the Nasdaq Capital Market and are not expected to trade in any market, however we anticipate that the shares of our common stock to be issued upon exercise of the pre-funded warrants will trade on the Nasdaq Capital Market.

We are an “emerging growth company,” as that term is used in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and, as such, we have elected to comply with certain reduced public company reporting requirements. See the section titled “Prospectus Summary — Implications of Being an Emerging Growth Company and a Smaller Reporting Company.”

Investing in our common stock involves a high degree of risks. See “Risk Factors” beginning on page 19. Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Per Pre-Funded Warrant	Total
Public offering price	\$	\$	\$
Underwriting discounts and commissions(1)	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$

¹⁾ Underwriting discounts and commissions do not include a non-accountable expense allowance equal to 1.0% of the public offering price payable to the underwriter, the reimbursement of certain expenses of the underwriter we have agreed to pay and certain other compensation. We refer you to “Underwriting” beginning on page 50 for additional information regarding underwriter’s compensation.

We have granted a 45-day option to the underwriter to purchase up to an additional _____ shares of our common stock (and/or pre-funded warrants in lieu thereof), representing 15% of the shares of common stock and pre-funded warrants sold in the offering solely to cover over-allotments, if any.

The underwriter expects to deliver the shares on or about _____, 2023.

ThinkEquity

The date of this prospectus is _____, 2023

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Neither we nor the underwriter have authorized anyone to provide you with information other than that contained in or incorporated by reference into this prospectus or any free writing prospectus prepared by or on our behalf or to which we have referred you. We and the underwriter take no responsibility for and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriter are offering to sell, and seeking offers to buy, securities only in jurisdictions where offers and sales are permitted. The information contained in or incorporated by reference into this prospectus is accurate only as of the date on the front cover page of this prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities. Our business, financial condition, results of operations and future prospects may have changed since that date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our securities or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

We and the underwriter are offering to sell, and seeking offers to buy, our shares of common stock and pre-funded warrants only in jurisdictions where offers and sales are permitted. Neither we nor any of the underwriter have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our shares of common stock and pre-funded warrants and the distribution of this prospectus outside of the United States.

Trademarks, Service Marks and Trade Names

We own, have applied for or have rights to use one or more registered and common law trademarks, service marks and/or trade names in connection with our business in the United States and/or in certain foreign jurisdictions.

This prospectus and our other public filings 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 prospectus and our other public filings is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus and our other public filings may appear without the ®, ™ 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 rights of the applicable owner of or licensor to these trademarks, service marks and trade names.

This prospectus contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other company.

On May 30, 2023, we received a Notice Of Allowance from the United States Patent and Trademark Office, or USPTO, allowing TRANSCODE THERAPEUTICS as a trademark under International Class 005, pharmaceutical preparations for the treatment of cancer, diagnostic preparations for medical purposes, having Serial Number 97/083236. For the purpose of this prospectus, TransCode Therapeutics® is referred to as TransCode. Additionally, “we”, “our”, “us” and the “company” refer to TransCode.

Where You Can Obtain More Information

We have filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-1 under the Securities Act of 1933, as amended, or the Securities Act, with respect to the securities offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our securities, we refer you to the registration statement, including the exhibits filed as a part of the registration statement of which this prospectus forms a part. Statements contained in this prospectus concerning the contents of any contract or any other documents are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

We are subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and we file reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is www.sec.gov. We also maintain a website at www.transcodetherapeutics.com. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC.

Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

Our code of conduct, corporate governance guidelines and the charters of our Audit Committee, Compensation Committee and Nomination and Corporate Governance Committee are available through the “Governance” portion of our website.

Incorporation by Reference

The SEC allows us to incorporate by reference the information and reports we file with it, which means that we can disclose important information to you by referring you to these documents. The information incorporated by reference is an important part of this prospectus and information that we file after the date hereof with the SEC will automatically update and supersede the information already incorporated by reference. We are incorporating by reference the documents listed below, which we have already filed with the SEC, and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, except as to any portion of any future report or document that is not deemed filed under such provisions, after the date of this prospectus and prior to the termination of this offering:

- > [our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 31, 2023;](#)
- > the information included in [our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 10, 2023](#), to the extent incorporated by reference into Part III of the [Annual Report on Form 10-K for the fiscal year ended December 31, 2022](#);
- > our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on [May 15, 2023](#) and for the quarter ended June 30, 2023, filed with the SEC on [August 14, 2023](#);
- > our Current Reports on Form 8-K filed with the SEC on [February 17, 2023](#), [March 31, 2023](#), [April 14, 2023](#), [May 10, 2023](#), [May 18, 2023](#), [May 19, 2023](#), [May 22, 2023](#), [June 8, 2023](#), [July 28, 2023](#), [August 4, 2023](#) and [August 24, 2023](#); and
- > the description of our common stock contained in our registration statement on [Form 8-A filed with the SEC on April 26, 2021](#), as supplemented by the description of our common stock contained in [Exhibit 4.1](#) to our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 31, 2023, and any amendment or report filed with the SEC for the purpose of updating such description.

Pursuant to Rule 412 under the Securities Act, any statement contained in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

Upon request, we will provide, without charge, to each person, including any beneficial owner, to whom a copy of this prospectus supplement is delivered, a copy of the documents incorporated by reference into this prospectus but not delivered with the prospectus. You may request a copy of these filings, and any exhibits we have specifically incorporated by reference as an exhibit in this prospectus, at no cost, by writing to us at the following address: Investor Relations Department, TransCode Therapeutics, Inc., 6 Liberty Square, #2382, Boston, Massachusetts 02109. These filings may also be obtained through our website located at <https://www.transcodetherapeutics.com>. The reference to our website is intended to be an inactive textual reference and, except for the documents incorporated by reference as noted above, the information on, or accessible through, our website is not intended to be part of this prospectus.

You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus or in the documents incorporated by reference is accurate as of any date other than the date on the front of this prospectus or those documents.

Reverse Stock Split

On May 23, 2023, we effected a reverse split of our common stock, shares either issued and outstanding or held by the Company as treasury stock, or the 2023 Reverse Split. The 2023 Reverse Split was previously

approved by the Board and shareholders of the Company. The 2023 Reverse Split was at a ratio of one share for every 20 shares previously held with no change in the par value per share. The 2023 Reverse Split did not change the number of authorized shares of common stock. All common stock share and per share data, and exercise price data for applicable common stock equivalents, included in this prospectus, have been retroactively adjusted to reflect the 2023 Reverse Split.

Prospectus Summary

This summary highlights selected information about us and this offering and does not contain all of the information that you should consider before investing in our securities. You should carefully read the entire prospectus and the documents incorporated by reference, especially the “Risk Factors,” as well as “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements, including the accompanying notes to those statements, incorporated herein by reference to our Form 10-K, our [Quarterly Report on Form 10-Q filed with the SEC on August 14, 2023](#) and our other filings with the SEC before making an investment decision. If any of the risks materialize or other events or conditions arise that we cannot predict, our business, financial condition, operating results and prospects could be materially and adversely affected. As a result, the price of our common stock could decline, and you could lose part or all of your investment. Some of the statements in this prospectus and the documents incorporated by reference constitute forward-looking statements that involve risks and uncertainties. See “Cautionary Note Regarding Forward-Looking Statements.” Our actual results could differ materially from those anticipated in such forward-looking statements as a result of certain factors, including those discussed in “Risk Factors” and other sections of this prospectus and the documents incorporated by reference.

Overview

TransCode is a platform delivery company focused on oncology, created on the belief that cancer can be defeated through the intelligent design and effective delivery of targeted therapeutics. Our lead therapeutic candidate, TTX-MC138, targets microRNA-10b, or miRNA-10b, a master regulator of metastatic cell viability in a range of cancers, including breast, pancreatic, ovarian, colon cancer, glioblastomas, and several others. In December 2022, TransCode received authorization from the U.S. Food and Drug Administration, or FDA, to conduct a Phase 0 clinical trial intended to demonstrate quantitative delivery of TTX-MC138 to metastatic lesions in subjects with advanced solid tumors. On April 25, 2023, we received Institutional Review Board, or IRB, approval from the Dana Farber Cancer Center to commence the trial at its affiliate, Massachusetts General Hospital, or MGH. In parallel, we completed IND-enabling toxicity studies with TTX-MC138 in support of our planned investigational new drug, or IND, application for a Phase I/II clinical trial with TTX-MC138. On August 23, 2023, we announced the dosing of the first subject in our First-in-Human Phase 0 clinical trial.

Our other preclinical program is a solid tumor program, TTX-siPDL1, an siRNA-based modulator of programmed death-ligand 1, or PD-L1. TransCode also has three cancer-agnostic programs in various stages of development, TTX-RIGA, an RNA-based agonist of the retinoic acid-inducible gene I, or RIG-I, targeting activation of innate immunity in the tumor microenvironment; TTX-CRISPR, a CRISPR/Cas9-based therapy platform for the repair or elimination of cancer-causing genes inside tumor cells; and TTX-mRNA, an mRNA-based platform for the development of cancer vaccines that activate cytotoxic immune responses against tumor cells.

All our therapeutic candidates are designed to utilize our proprietary delivery system with the goal of delivering therapeutic payloads safely and accurately to tumors and metastases with the goal of significantly improving outcomes for cancer patients.

Recent Developments

First Subject Dosed

On August 23, 2023, we announced the dosing of the first subject in our First-in-Human Phase 0 clinical trial. The Phase 0 trial is an open-label, single-center, microdose study intended to demonstrate delivery of the radio-labeled version of our lead therapeutic candidate, TTX-MC138, to radiographically-confirmed metastases in subjects with advanced solid tumors. The subject received a single subtherapeutic dose of radiolabeled TTX-MC138 and appeared to tolerate the dosing well. Analysis and monitoring of data from this subject is ongoing including results of positron emission tomography-magnetic resonance imaging (PET-MRI), to determine uptake of TTX-MC138 to the subject’s metastatic lesions. Enrollment of additional subjects is also currently underway.

A Phase 0 clinical trial is an exploratory study conducted under an Investigational New Drug application. Up to 12 subjects may be enrolled in this clinical trial, each of which is intended to receive a single microdose of radiolabeled TTX-MC138 followed by PET-MRI. The trial is intended to quantify the amount of TTX-MC138 delivered to metastatic lesions and the pharmacokinetics of the therapeutic candidate in cancer subjects, but not to have a therapeutic effect. The trial could yield critical data regarding therapeutic dosing, timing, and potential safety that could inform later clinical trials, including a Phase 1 trial planned to commence in 2024.

NIH SBIR Award

On April 3, 2023, we received a Notice of Award from the National Institutes of Health confirming the availability of the third tranche of funding under the award we received in April of 2021. On April 11, 2023, we drew down the third tranche of the Award in the amount of \$870,684. The total award was for approximately \$2.4 million; we received approximately \$309 thousand in the first tranche and approximately \$1.1 million in the second tranche. The staff at the National Cancer Institute proposed that TransCode submit an application for an SBIR Phase IIB application to extend the studies in the original SBIR. On August 21, 2023, we submitted a proposal for the Phase IIB award totaling \$4.5 million over two years, scheduled to commence in April 2024, if awarded.

TTX-MC138 IND-enabling studies

We completed IND-enabling toxicity studies for TTX-MC138 in two species of animals with very favorable results. No mortality or unacceptable toxicity were seen even at the highest feasible dose tested, reflecting the safety profile of the therapeutic. Upon completion of our FDA briefing book which will include relevant information that we previously filed in the nearly 3,800 page eIND application late in 2022 which the FDA approved less than a month after submission, we plan to file an IND with FDA as soon as practical to conduct a Phase I/II clinical trial with TTX-MC138. The scale up and manufacturing of GMP drug product for the IND enabling studies was completed along with production of final drug product for the Ph I/II to treat patients in late August 2023.

Feline Case Study with Spontaneous Breast Cancer

To test the applicability of our therapeutic strategy in a larger animal, our scientific co-founders conducted a case study with a feline that had developed spontaneous mammary carcinoma, or FMC, the third most common cancer in cats, which is also highly metastatic. FMC has high resemblance to human breast cancer compared to mammary carcinomas of other companion animals in terms of relative age at onset, incidence, risk factors, prognostic aspects, histopathology, biological behavior, metastatic pattern and response to therapy. In the case study, a feline patient that had previously failed multiple rounds of standard-of-care treatment for advanced metastatic FMC and was at the end of her life expectancy was dosed with TTX-MC138. Delivery of TTX-MC138 to the metastatic lesions was demonstrated using noninvasive magnetic resonance imaging. Dosing with TTX-MC138 resulted in durable inhibition of the miR-10b target and induction of the downstream metastasis suppressor, HOXD10, lasting as long as three months after injection. The patient tolerated the injection well with no adverse effects and vital signs remained within the normal range. Additionally, seven weeks after the first dose, the feline patient was dosed a second time and tolerated the injection well. The patient survived for approximately five months compared to its life expectancy prior to dosing. Subsequently, additional animals have been enrolled in the trial. This trial has demonstrated delivery to the metastatic lesions and target inhibition in the brain tumors. Also, it has demonstrated safety of a dosing regimen comprising six doses (two doses biweekly for the first month followed by four monthly doses). Importantly, the trial demonstrated stable disease despite initiating treatment when disease was at a very advanced stage with widely present lung metastases. Notwithstanding the need for additional therapeutic and toxicology studies, we believe that in combination with our other preclinical findings, this case study suggests the robustness and potential tolerability of therapy with TTX-MC138.

Positive Preclinical Results with TTX-MC138 in Pancreatic Adenocarcinoma

We recently evaluated the efficacy of TTX-MC138 as monotherapy in a murine model of pancreatic adenocarcinoma and achieved positive preclinical results. In this study, we treated mice bearing human

pancreatic tumors with TTX-MC138 once weekly for eight weeks. The candidate demonstrated a pharmacodynamic response by successfully inhibiting miR-10b. Serum miR-10b was down-regulated by TTX-MC138 and was shown to be a potential surrogate biomarker of therapeutic efficacy, opening up the possibility of noninvasive monitoring of therapeutic response in human patients. Forty percent (40%) of animals treated with TTX-MC138 had complete responses, defined as complete regression of disease and long-term survival without recurrence.

These new findings expand the potential therapeutic relevance of TTX-MC138 beyond breast cancer, in which activity had previously been shown in preclinical studies, to include pancreatic adenocarcinoma. However, there is no assurance that these preclinical results will be duplicated in further preclinical studies or in cancer patients suffering from pancreatic cancer.

Positive Preclinical Results in Glioblastoma

Recent studies have shown that miR-10b is highly expressed in high-grade glioblastoma multiforme, and its inhibition leads to dysregulation of multiple pathways in tumorigenesis, resulting in repression of tumor growth and increased apoptosis. Thus, we hypothesized that suppressing miR-10b could enhance the cytotoxicity of conventional GBM chemotherapy with temozolomide, or TMZ. A recent study conducted with our scientific co-founder, Dr. Anna Moore, at Michigan State University was published in *Frontiers in Molecular Biosciences* (see Recent Publications).

Inhibition of miR-10b in glioblastoma cells was achieved using MN-anti-miR10b (a TTX-MC138 analogue). Treatment of U251 and LN229 human glioblastoma cells led to inhibition of miR-10b accompanied by repression of growth and an increase in apoptosis. We next explored whether MN-anti-miR10b could enhance the cytotoxic effect of TMZ. During these studies, we unexpectedly found that TMZ monotherapy increased miR-10b expression and changed the expression of corresponding miR-10b targets. This discovery led to our design of a sequence-dependent combination treatment, in which an initial administration of MN-anti-miR10b resulting in miR-10b inhibition and induction of apoptosis was, in turn, followed by administration of a sub-therapeutic dose of TMZ causing cell cycle arrest and ultimately cell death.

Orphan Drug Designation

TTX-siPDL1

In June 2022, we received Orphan Drug Designation from the FDA for our TTX-conjugated small interfering RNA against PD-L1, a candidate for treatment of pancreatic cancer. The designation was granted based on positive results achieved in *in vivo* studies treating human pancreatic tumors implanted in animals.

TTX-MC138

In addition, we conducted preclinical *in vivo* studies with TTX-MC138 in a pancreatic cancer model and submitted data to the FDA requesting Orphan Drug Designation which we received on February 27, 2023. We intend to conduct additional *in vivo* studies to support filings of other TTX-based therapeutic candidates in other orphan disease indications including osteosarcoma, glioblastoma, and small cell lung cancer. There is no assurance that we will receive any additional designations.

New Patent Applications

TTX-RIGA

TransCode converted U.S. Provisional Patent Application No. 63/356,449 on June 28, 2023 into an international application (PCTG/US/2023/026460) and a U.S. utility application (18/215,550). This filing discloses the use of nucleic acid-based agonists of RIG-I singly or in combination with a radiolabeled nanoparticle for activation of the innate immune system that we anticipate will lead to tumor cell death.

TTX-beta

TransCode filed U.S. Provisional Patent Application No. 63/456,602 entitled *Nanoparticles Comprising Payloads and their In Vivo Delivery* on April 3, 2023, disclosing novel iron oxide nanoparticles able to deliver therapeutic payloads for the treatment of disease.

Target Binding Scaffolds

TransCode filed U.S. Provisional Patent Application No. 63/464,469 entitled *Nanoparticles comprising target binding scaffold proteins and their in vivo delivery* on May 5, 2023, disclosing novel nanoparticles complexed with polypeptide-based payloads designed to target proteins of interest for the diagnosis and treatment of disease.

There is no assurance that we will successfully convert any provisional patent application or that, if converted, any patents will issue therefrom.

Licensing Option

On May 9, 2022, we executed an option agreement with MGH giving TransCode the right to negotiate an exclusive, worldwide, royalty-bearing license related to a radiotheranostic technology disclosed in patent application PCT/US2021/057912 entitled THERAPEUTIC, RADIOLABELED NANOPARTICLES AND METHODS OF USE THEREOF. We expect to finalize negotiations of a license to this technology in the near term, but there is no assurance that any license will be effected.

Targeted Therapeutic Delivery Background

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

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

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

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

Delivery System

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

The TTX technology has gone through over 18 years of research and development, or R&D, and optimization, including 12 years at Harvard Medical School and the Massachusetts General Hospital, by our scientific co-founders prior to company formation. As an expansion of the original platform design, we recently submitted U.S. provisional patent applications US 63/464,469 and US 63/456,602 as part of our next generation IONP delivery platform. We believe that this expanded use platform has the potential to broaden TTX's targeted therapeutic delivery to include both mRNA vaccines as well as CRISPR candidates to tumors and metastases. The increased delivery opportunity could allow us to participate in additional rapidly growing global marketplaces. According to a recent analysis by Emergen Research, the global CRISPR Technology Market is expected to reach \$3.94 billion by 2027. The global mRNA therapeutics market size was estimated to reach \$33.82 billion in 2023 and is projected to grow at a compound annual growth rate of 24.58% to reach \$158.20 billion by 2030 according to an April 2023 360iResearch™ publication.

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

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

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

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

Advancing new RNA therapies through a modular approach

The TransCode TTX platform is modular by design, both at the level of the core nanoparticle and at the therapeutic loading. The size, charge, and surface chemistry of the core nanoparticles are designed to be tuned

to optimize them for the intended target and therapeutic load. Also, the therapeutic load is designed to be adapted to the specific approach being developed, ranging from RNAi which includes small interfering RNAs, or siRNAs, antisense oligonucleotides, non-coding RNA mimics to mRNA-based cancer vaccines, and Clustered Regularly Interspaced Palindromic Repeats, or CRISPR, -based gene repair and replacement platforms as well as Pattern Recognition Receptors such as RIG-I.

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

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

Dr. Medarova’s paper suggests that the radiolabeling does not impact tumor cell uptake or the ability of TTX-MC138 to engage its target. The paper also shows that the biodistribution of Cu-64 labeled TTX-MC138, when injected at a microdose, reflects its biodistribution at the level of a therapeutic dose.

These key findings are expected to enable a microdosing study with TTX-MC138 in patients which we believe:

- (i) allows precise quantitation of the amount of TTX-MC138 delivered to the metastatic lesions because of the higher sensitivity and quantitative accuracy of positron emission tomography;
- (ii) permits measurement of the pharmacokinetics and biodistribution of TTX-MC138 not only in the metastatic lesions but in other tissues throughout the body. This knowledge can inform Phase I/II clinical trial designs by allowing us to determine drug uptake and clearance from vital organs;
- (iii) enables measurement of pharmacokinetic endpoints potentially informing dosing for Phase II/III clinical trials. Specifically, because of the high sensitivity and quantitative nature of PET-MRI, it may be possible to derive a more precise calculation of drug concentration in the metastatic lesions over time and then correlate that information to the effective dose defined in our preclinical studies; and

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

Because of the benefits we believe we can derive from a microdosing Phase 0 trial, and reflecting the studies described in Cancer Nanotechnology, we are conducting a Phase 0 trial as our First-in-Human clinical trial to demonstrate delivery to tumors and metastases with high efficiency.

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

The Phase 0 study, is an open-label, single-center, microdose study to demonstrate delivery of TTX-MC138-NODAGA-Cu64 (radio-labeled version of our lead candidate therapeutic) to radiographically confirmed metastases in subjects with advanced solid tumors. In the study, we may enroll up to 12 patients with late-stage advanced solid tumors, and use PET-MRI to measure TTX-MC138 delivery to metastatic lesions and other tissues in the body. We are conducting the clinical portion of the study at a major cancer center in Boston, MA. As of the date of this prospectus, we have dosed and imaged one patient and expect additional patients to consent to participate in the trial before year end. Depending on the results with the first four patients, which are intended to be more extensively evaluated, we may end the trial after completing the protocol with those four patients.

Our Lead Therapeutic Candidate

Our scientific co-founders developed TransCode's lead therapeutic candidate at The General Hospital Corporation, d/b/a Massachusetts General Hospital to target microRNA-10b, a well-validated biomarker linked to metastatic cancer. In contrast, most anti-cancer therapies target primary tumors and do not address metastatic disease specifically. MicroRNA-10b has been shown to be the master regulator of metastatic disease in multiple tumor types. We believe effective therapeutics have not been developed targeting microRNA-10b because of challenges in delivering therapeutics to tumors despite microRNA-10b's strong association with cancer metastasis as documented in over 700 peer-reviewed scientific publications.

TTX-MC138 comprises proprietary iron-oxide nanoparticles conjugated to sequence-specific LNA/DNA oligonucleotides that target microRNA-10b. The nanoparticles serve as a vehicle to deliver oligonucleotides to tumors and metastases. The magnetic properties of these nanoparticles allow for monitoring their delivery using non-invasive imaging, which we believe adds value for clinical implementation of this therapeutic approach.

Preclinical Study Results Breast Cancer

Our scientific co-founders conducted a variety of preclinical animal studies involving human metastatic breast cancer models. In these studies, TTX-MC138 was successfully delivered to metastatic lesions in the lymph nodes, lungs, and bones as shown by non-invasive imaging performed 24 hours after injection. In five separate studies involving over 125 mice, TTX-MC138 was injected into mice implanted with human metastatic breast tumors. These mouse models included the rodent 4T1-luc2 orthotopic allograft, which is a very aggressive model of stage IV metastatic breast cancer, the human MDA-MB-231-luc-D3H2LN xenograft, which is a stage II/III cancer model, and the human MDA-MB-231-BrM2-831 xenograft, which is a model of breast cancer metastatic to the brain. Tumors in mice implanted with MDA-MB-231 cells typically progress from localized disease to lymph node metastases within 21 days of implantation. Tumors in mice implanted with 4T1-luc2 cells typically progress to distant sites in the animals within 10 days of implantation.

To test TTX-MC138 in the model of lymph node metastatic breast cancer, mice had their primary tumors surgically removed four to five weeks after tumor inoculation, following confirmation of lymph node metastases via imaging. This was done to better simulate a clinical scenario, since the current standard of care involves surgical removal of the primary tumor in patients with lymph node metastatic breast cancer. Treatment with TTX-MC138 was then initiated during the week of tumor removal. Because tumors in mice

replicate more rapidly than is typical in humans, we combined low-dose doxorubicin with the TTX-MC138 because doxorubicin slows metastatic cell replication specific to these tumor models. Doing so allowed the TTX-MC138 to more efficiently reach and inhibit the miR-10b inside the tumor cells.

After four weeks of therapy, metastases in mice treated with TTX-MC138 regressed. By contrast, in the control groups, there was metastatic progression (Within-Subjects ANOVA: $p < 0.05$). Treatment was discontinued once complete metastatic regression was observed. By the end of the study at 12 weeks, there was no recurrence and 100% survival in treated subjects having this cancer model. In similar studies involving mice implanted with 4T1-luc2 breast tumors, we observed regression of distant metastases by week six, at which point treatment was stopped (Within-Subjects ANOVA: $p < 0.05$). Despite stopping treatment, the animals remained metastasis-free and by the end of the study, no recurrence of disease had been observed. There was evidence of complete regression without recurrence in 65% of treated subjects while 35% progressed due to insufficient inhibition of miR-10b in this group. We believe this was due to the high rate of tumor cell replication in this model resulting in dilution of the therapeutic. We do not expect this to be the case in humans with metastatic disease, in whom tumor cell replication is dramatically slower than in mice.

Pancreatic Cancer

We recently evaluated the efficacy of TTX-MC138 as monotherapy in a murine model of pancreatic adenocarcinoma and achieved positive preclinical results. In this study, we treated mice bearing human pancreatic tumors with TTX-MC138 once weekly for eight weeks. The candidate demonstrated a pharmacodynamic response by successfully inhibiting miR-10b. Serum miR-10b was down-regulated by TTX-MC138 and was shown to be a potential surrogate biomarker of therapeutic efficacy, opening up the possibility of noninvasive monitoring of therapeutic response in human patients. Forty percent (40%) of animals treated with TTX-MC138 had complete responses, defined as complete regression of disease and long-term survival without recurrence.

These new findings expand the potential therapeutic relevance of TTX-MC138 beyond breast cancer, in which activity had previously been shown in preclinical studies, to include pancreatic adenocarcinoma. However, there is no assurance that these preclinical results will be duplicated in further preclinical studies or in cancer patients suffering from pancreatic cancer.

Glioblastoma

Recent studies have shown that miR-10b is highly expressed in high-grade glioblastoma multiforme, or GBM, and its inhibition leads to dysregulation of multiple pathways in tumorigenesis, resulting in repression of tumor growth and increased apoptosis. Thus, we hypothesized that suppressing miR-10b could enhance the cytotoxicity of conventional GBM chemotherapy with temozolomide, or TMZ. Inhibition of miR-10b in glioblastoma cells was achieved using MN-anti-miR10b (a TTX-MC138 analogue). Treatment of U251 and LN229 human glioblastoma cells with our drug candidate led to inhibition of miR-10b accompanied by repression of growth and increase in apoptosis. We next explored whether MN-anti-miR10b could enhance the cytotoxic effect of TMZ. During these studies, we unexpectedly found that TMZ monotherapy increased miR-10b expression and changed the expression of corresponding miR-10b targets. This discovery led to the design of a sequence-dependent combination treatment, in which miR-10b inhibition and induction of apoptosis by MN-anti-miR10b was followed by a sub-therapeutic dose of TMZ, which caused cell cycle arrest and ultimately tumor cell death. Additionally, studies in human patient-derived models of GBM confirmed delivery to the brain tumors and exhibited a highly significant level of target inhibition, indicating robust pharmacodynamic activity.

Ongoing and Planned Clinical Trials

We submitted an eIND application to the FDA on November 30, 2022, to conduct a First-in-Human, or FIH, clinical trial with TTX-MC138-NODAGA-Cu64 and received written authorization from the agency on December 23, 2022, allowing us to proceed with the clinical trial. On April 25, 2023, we received authorization from the IRB to proceed with the trial in up to 12 cancer patients with advanced solid tumors. This clinical

trial involves injecting a single microdose of radiolabeled TTX-MC138, termed TTX-MC138- NODAGA-Cu64, into cancer patients with advanced solid tumors. Injections are to be followed by imaging using integrated positron emission tomography-magnetic resonance imaging, or PET-MRI. The Phase 0 trial is intended to quantify the amount of radiolabeled TTX-MC138 delivered to metastatic lesions and the pharmacokinetics (PK) and biodistribution of the therapeutic candidate in cancer patients. The single dose involved in this trial is not expected to demonstrate target engagement. The Phase 0 trial could yield critical data regarding therapeutic dose, timing, and potential safety that could inform later clinical trials. We believe that demonstrating our ability to overcome the challenge of RNA delivery to genetic targets outside the liver, and specifically to tumors and metastases, would represent a major step forward in unlocking therapeutic access to genetic targets involved in a range of cancers. We commenced enrollment of the Phase 0 trial during the third quarter of 2023 and anticipate announcing preliminary, topline data from initial patients in this trial in the fourth quarter of 2023. Concurrent with the Phase 0 trial, we have completed IND-enabling toxicity studies to support the filing of our IND for a Phase I/II clinical trial with TTX-MC138. On April 24, 2023, we submitted a pre-IND briefing package to the FDA regarding our planned Phase I/II clinical trial and development plans and received a written response from FDA on May 24, 2023.

Modular Design Toolbox

We employ a design engine to enable development of RNA therapeutic candidates that we believe can be efficiently delivered to genetic targets inside tumor cells. This approach is based on four complementary elements that together address the challenges of RNA drug development in oncology:

Nanocarrier Delivery Mechanism — Our strategy seeks to leverage a nanoparticle that has been extensively used in humans for imaging by repurposing it to deliver targeted therapeutics to oncology targets and for other therapeutic applications. The nanocarrier is tunable to pre-designed specifications to deliver therapeutic oligonucleotides to an RNA target in tumors and metastases without compromising its integrity. These nanocarriers differentiate us from competitive delivery approaches, many of which rely on lipid nanoparticles or chemical structures, such as GalNAc. Competitive delivery approaches effectively target sites in the liver but not sites in tumors and metastases elsewhere. Our nanocarrier is derived from, and is chemically similar to, nanoparticles extensively used in imaging (Feridex, from Advanced Magnetix) or for treating iron deficiency anemia (Feraheme, also from Advanced Magnetix).

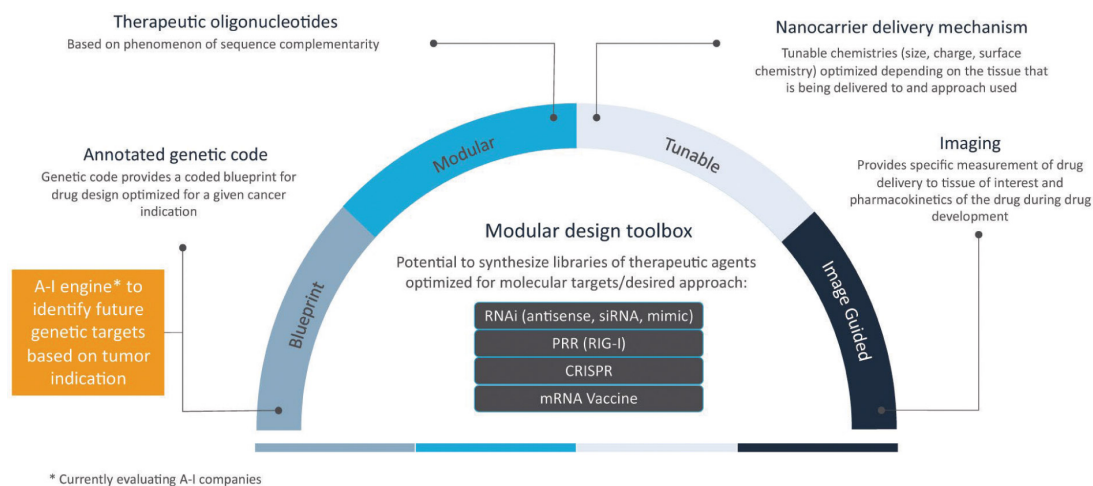
We expect that our competitive advantages will include effectively reaching tumors and metastases, achieving robust target engagement in tumor cells, and an anticipated wide therapeutic window based on prior experience in preclinical models and clinical experience of others with similar iron oxide nanoparticles.

Genetic Code — Our approach to drug development takes advantage of our rapidly expanding knowledge about the human genome and the annotation of the genome — the knowledge about what different genes are responsible for, especially in cancer. Armed with this knowledge, we can take advantage of the coded nature of the genome to design therapeutic or diagnostic agents. Specifically, once we determine the code of the cancer target, we can develop therapeutic candidates using specific nucleic acids that are harmonized to that target and potentially rewrite the story on cancer. This is what TransCode means — to change the code. After determining the genetic target of interest, we may be able to choose from a variety of RNA approaches best suited for that target. Those approaches will likely range from RNAi, which include siRNAs, antisense oligonucleotides, and non-coding RNA mimics; messenger RNA-based cancer vaccines; CRISPR-based gene repair and replacement platforms; or Pattern Recognition Receptors like RIG-I.

Modular Design for Therapeutic Development — Our discovery platform consists of a modular ‘toolbox’ for developing therapeutic candidates designed to attack specific disease-causing RNA targets based on the phenomenon of genetic complementarity. These therapeutic candidates incorporate synthetic oligonucleotides, or oligos, that can be designed as antagomirs, mimics, miRNA sponges, siRNA duplexes, ribozymes, and others depending on the desired therapeutic strategy. In addition to the varied oligo design approach, we can also synthesize nanocarriers with tunable chemistry properties to enable delivery of CRISPR genome editing tools and mRNAs. Combined, the modularity and tunability of these oligonucleotides and nanocarrier components may enable the potential to synthesize libraries of therapeutic agents designed for a

given indication or a given patient in terms of therapeutic oligonucleotide design, size, surface coating and charge, hydrophilicity and hydrophobicity, and antigen-targeting through incorporation of targeting peptides.

Image Guided — Because our therapeutic candidates are innately detectable using non-invasive imaging, we can monitor their delivery to the tissue of interest and measure their bioavailability. The ability to monitor delivery using Magnetic Resonance Imaging, or MRI, can be instrumental in assessing and controlling the amount of oligonucleotide that reaches targeted tissues. MRI use during the design phase of the therapeutic candidate could guide drug design, delivery schedule, route, and dose and could suggest alternatives should treatment with the therapeutic candidate fail in a given patient. This is critical during drug development because it should allow us to optimize drug design to maximize therapeutic effect.



Recent Publications

In collaboration with scientists from MGH, Harvard Medical School and Michigan State University, we have published the five manuscripts listed below. The publication by Smith et al. reviews recent progress towards translating short non-coding RNAs into the clinic. The manuscript by Le Fur et al. describes a method for radiolabeling our lead candidate, TTX-MC138, and employing PET-MRI to assess the tissue distribution of microdoses of the therapeutic candidate. This manuscript serves as the basis for our FIH clinical trial. The publication by Chen et al. reviews key microRNA targets, including miR-10b, in glioblastoma. The fourth study, by Moore et al., presents a case study of a feline patient with metastatic breast cancer treated with TTX-MC138.

Clinical Applications of Short Non-Coding RNA-Based Therapies in the Era of Precision Medicine. Smith ES, Whitty E, Yoo B, Moore A, Sempere LF, Medarova Z. *Cancers (Basel)*. 2022 Mar 21;14(6):1588.

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. Le Fur M, Ross A, Pantazopoulos P, Rotile N, Zhou I, Caravan P, Medarova Z, Yoo B. *Cancer Nanotechnol*. 2021;12(1):16.

Role of microRNAs in glioblastoma.

Chen M, Medarova Z, Moore A. *Oncotarget*. 2021 Aug 17;12(17):1707-1723.

Case Report: microRNA-10b as a Therapeutic Target in Feline Metastatic Mammary Carcinoma and its Implications for Human Clinical Trials. Moore A, Savan NA, Saavedra PV, Halim A, Yuzbasiyan-Gurkan V, Wang P, Yoo B, Kiupel M, Sempere L, Medarova Z. *Front. Oncol. Sec. Cancer Molecular Targets and Therapeutics* doi: 10.3389/fonc.2022.959630.

Co-administration of Temozolomide (TMZ) and the Experimental Therapeutic Targeting miR-10b, Profoundly Affects the Tumorigenic Phenotype of Human Glioblastoma Cells. Ming Chen, Bryan Kim, Neil Robertson, Sujan K. Mondal, Zdravka Medarova, Anna Moore *Frontiers in Molecular Biosciences* 2023;

In addition to the five publications described above, we submitted a manuscript describing the feasibility of our RIG-I targeting approach using our TTX-RIGA candidate which was recently published in BioRxiv.

Summary of 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 prospectus or incorporated by reference herein, including in the section entitled “Risk Factors”, and include, but are not limited to, the following:

- our immediate low cash position and our estimates and expectations regarding our capital requirements, cash and expense levels, liquidity sources and our ability to obtain, on satisfactory terms or at all, the financing required to support operations, research, development, clinical trials, and commercialization of products;
- our business is highly dependent on the success of TTX-MC138, our lead therapeutic candidate which is at the early stages of development. Our therapeutic and diagnostic candidates require significant additional preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially;
- a potential delisting of our common stock from trading on the Nasdaq Capital Market if our stockholders’ equity does not meet and maintain the \$2.5 million minimum Nasdaq threshold;
- the results and timing of our preclinical and clinical trial activities;
- if we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- our ability to expand our therapeutic candidate portfolio through internal research and development or the acquisition or in-licensing of intellectual property assets;
- the therapeutic benefits, effectiveness and safety of our therapeutic candidates;
- our ability to receive regulatory approval for our therapeutic candidates in the United States, Europe and other geographies;
- the expected regulatory approval pathway for our therapeutic candidates;
- potential changes in regulatory requirements, and delays or negative outcomes from the regulatory approval process;
- our reliance on third parties for the planning, conduct and monitoring of clinical trials, for the manufacture of clinical drug supplies and drug product and for other requirements;
- our estimates of the size and characteristics of the markets that may be addressed by our therapeutic candidates;
- market acceptance of our therapeutic candidates that are approved for marketing in the United States or other countries;
- our ability to successfully commercialize our therapeutic candidates;
- the impact of natural disasters, global pandemics (including further outbreaks of existing strains of COVID-19 or new strains of the virus), labor disputes, lack of raw materials or other supplies, issues with facilities and equipment or other forms of disruption to business operations at our manufacturing or laboratory facilities or those of our vendors, or at clinical trial sites;
- our ability to utilize our proprietary technological approach to develop and commercialize our therapeutic candidates;
- our heavy dependence on licensed intellectual property, including our ability to source and maintain licenses from third-party owners;
- our ability to attract, retain and motivate key personnel;

- our ability to generate revenue and become profitable;
- our reliance on third-party manufacturers to manufacture our drug substance and drug product that meets with our design specifications;
- our dependance on contract research organizations and other institutions to manage our clinical trials;
- 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 therapeutic candidates may not be predictive of the results of later-stage clinical trials;
- 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 therapeutic candidates;
- quality problems could delay or prevent delivery of our materials for clinical trials or to the market;
- changes in methods of therapeutic candidate manufacturing or formulation may result in additional costs or delays;
- our therapeutic 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;
- if we are unable to advance our therapeutic candidates to clinical development, obtain regulatory approval and ultimately commercialize our therapeutic candidates or if we experience significant delays in doing so, our business will be materially harmed;
- even if we receive regulatory approval of TTX-MC138 or any of our other therapeutic 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 therapeutic candidates;
- 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;
- ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations;
- 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.
- obtaining and maintaining regulatory approval for our therapeutic candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that or of any of our other therapeutic candidates in other jurisdictions;
- we face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do;
- the price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock;
- we have broad discretion in the use of the net proceeds from this offering and may not use them effectively;
- investors may incur dilution in the net tangible book value of the shares purchased in the offering, assuming no sale of any pre-funded warrants in lieu of common stock;
- 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 and the trading price of our common stock; and

- other risks and uncertainties, including those listed under the caption “Risk Factors” in our Annual Report on Form 10-K and in our other regulatory filings, including our Quarterly Report on Form 10-Q filed with the SEC on August 14, 2023.

Corporate Information

We were incorporated in the State of Delaware in January 2016. Our corporate address is 6 Liberty Square, #2382, Boston, Massachusetts 02109; our telephone number is (857) 837-3099. Our website is www.transcodetherapeutics.com. Information contained in, or that can be accessed through, our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus. Our design logo and our other registered and common law trade names, trademarks and service marks are the property of TransCode.

Implications of being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies.

These provisions include those that allow us to:

- provide only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- make reduced disclosure about our executive compensation arrangements;
- hold no non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exempt us from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering (i.e., December 31, 2026); (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Additionally, 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. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company, and we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies.

We are also a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies (i) until the fiscal year following the determination that the market value of our voting and non-voting common stock held by non-affiliates is more than \$250 million measured on the last business day of our second fiscal quarter, or (ii) if our annual revenues are less than \$100 million during the most recently completed fiscal year, until the fiscal year following the determination that the market value of our voting and non-voting common stock held by non-affiliates is more than \$700 million measured on the last business day of our second fiscal quarter.

The Offering

Common Stock offered by us	shares of our common stock (shares if the underwriter exercises its over-allotment option in full).
Pre-funded warrants offered by us	<p>We are also offering to those purchasers, if any, whose purchase of the common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if they so choose, pre-funded warrants in lieu of the common stock that would otherwise result in ownership in excess of 4.99% (or 9.99%, as applicable) of our outstanding common stock.</p> <p>The purchase price of each pre-funded warrant will equal the price per share of common stock being sold to the public in this offering, minus \$0.01, and the exercise price of each pre-funded warrant will be \$0.01 per share.</p> <p>For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis.</p> <p>Each pre-funded warrant will be immediately exercisable and may be exercised at any time until exercised in full. There is no expiration date for the pre-funded warrants. To better understand the terms of the pre-funded warrants, you should carefully read the “Description of Capital Stock” section of this prospectus. You should also read the form of pre-funded warrant, which is filed as an exhibit to the registration statement that includes this prospectus.</p>
Common Stock to be outstanding after this offering(1)	shares of common stock (shares if the underwriter exercises its over-allotment option in full), assuming no sale of any pre-funded warrants. To the extent pre-funded warrants are sold, it will reduce the number of shares of common stock sold in this offering on a one-for-one basis until such warrants are exercised, if ever.
Over-Allotment Option	<p>The underwriter has an option for a period of 45 days to purchase up to additional shares of our common stock and/or pre-funded warrants to cover over-allotments, if any.</p> <p>The purchase price to be paid by the underwriters per additional share of common stock or pre-funded warrant shall be equal to the public offering price of one share of common stock or pre-funded warrant, as applicable, less the underwriting discount.</p>
Use of Proceeds	We intend to use the net proceeds of this offering (i) to fund one or more clinical trials of TTX-MC138, our lead therapeutic candidate, including related IND-enabling studies; and (ii) for working capital and general corporate purposes. See “Use of Proceeds” for more information.
Nasdaq Capital Market Symbol for Common Stock	RNAZ

Lock-up Agreements	<p>We do not intend to apply for the listing of the pre-funded warrants on any national securities exchange or other trading system. Without an active trading market, the liquidity of the pre-funded warrants will be limited.</p>
Underwriter’s Warrants	<p>The company and our directors, officers and certain of our stockholders have agreed with the underwriter, subject to certain exceptions, not to sell, transfer or dispose of, directly or indirectly, any of our common stock or securities convertible into or exercisable or exchangeable for our common stock for a period of three months with respect to the company (or two months if gross proceeds from this offering are less than \$10 million), and for a period of six months with respect to our directors, officers and certain of our stockholders after the date of this prospectus. See “<i>Underwriting</i>” for more information.</p>
Risk Factors	<p>The registration statement of which this prospectus is a part also registers for sale warrants to purchase _____ shares of our common stock (_____ shares if the underwriter exercises its over-allotment option in full) which we will issue to the underwriter as a portion of the underwriting compensation payable to the underwriter in connection with this offering. The warrants will be exercisable for a four-and-one-half year period commencing 180 days following the effective date of the registration statement of which this prospectus is a part, at an exercise price equal to 125% of the public offering price of the common stock. See “<i>Underwriting — Underwriter’s Warrants</i>” for a description of these warrants.</p> <p>Investing in our securities involves a high degree of risk. See “<i>Risk Factors</i>” for important information.</p>
<p>¹⁾ The number of shares of common stock to be outstanding after the offering is based on 1,950,674 shares of common stock outstanding as of June 30, 2023, and excludes, as of that date, the following:</p> <ul style="list-style-type: none"> ➤ 267,277 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of \$10.84 per share; ➤ 15,625 shares of common stock issuable upon the exercise of outstanding IPO Underwriter Warrants at an exercise price of \$100.00 per share; ➤ 9,962 shares of common stock issuable upon exercise of outstanding February 2023 Placement Agent Warrants at an exercise price of \$13.18 per share; ➤ 6,250 shares of common stock issuable upon exercise of outstanding Consultant Warrants at an exercise price of \$10.00 per share; ➤ 950,000 shares of common stock issuable upon the exercise of outstanding June 2023 Pre-funded Warrants at an exercise price of \$0.01 per share; ➤ 140,000 shares of common stock issuable upon the exercise of outstanding June 2023 Placement Agent Warrants at an exercise price of \$4.38 per share; ➤ 2,000,000 shares of common stock issuable upon the exercise of outstanding Series A-1 Warrants at an exercise price of \$3.25 per share; ➤ 2,000,000 shares of common stock issuable upon the exercise of outstanding Series A-2 Warrants at an exercise price of \$3.25 per share; ➤ 4,479 shares of common stock reserved for future issuance under our 2021 Stock Option and Equity Incentive Plan, or the 2021 Plan; and 	

- 16,500 shares of common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, or our 2021 ESPP.

Except as otherwise indicated herein, all information in this prospectus assumes the following:

- no exercise by the underwriter of the over-allotment option to purchase additional shares (or pre-funded warrants in lieu thereof);
- no exercise of outstanding options or warrants;
- no exercise of the underwriter's warrants to be issued upon consummation of this offering at an exercise price equal to 125% of the initial offering price of the common stock; and
- no sale of any pre-funded warrants in this offering.

Summary Financial Data

You should read the following summary financial data together with the section entitled “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” and our financial statements and related notes for the year ended December 31, 2022, and for the six months ended June 30, 2023, appearing in our Annual Report on Form 10-K for the Fiscal Year Ended December 31, 2022, and [Quarterly Report on Form 10-Q for the Three and Six Months Ended June 30, 2023](#), incorporated herein by reference. The following summary statement of operations data for the years ended December 31, 2022 and 2021, are derived from our audited financial statements appearing in our [Annual Report on Form 10-K for the Fiscal Year Ended December 31, 2022](#), incorporated herein by reference. We have derived the summary statements of operations data for the six months ended June 30, 2023 and 2022, and balance sheet data as of June 30, 2023, from our unaudited interim financial statements appearing in our [Quarterly Report on Form 10-Q for the Three and Six Months Ended June 30, 2023](#), incorporated herein by reference. We have prepared the unaudited interim financial statements on the same basis as the audited financial statements and have included all adjustments, consisting only of normal recurring adjustments that, in management’s opinion, are necessary to state fairly the information set forth in those financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future and our results for the six months ended June 30, 2023, are not necessarily indicative of the results that may be expected for the full year ending December 31, 2023, or any other period. The summary financial data in this section are not intended to replace our financial statements and related notes and are qualified in their entirety by the financial statements and related notes incorporated herein by reference.

	<u>Six Months Ended June 30,</u>		<u>Years Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>	<u>2022</u>	<u>2021</u>
Unaudited				
Statement of Operations Data				
Operating expenses				
Research and development	\$ 5,557,260	\$ 4,501,604	\$ 10,232,366	\$ 2,753,966
General and administrative	4,474,688	3,683,191	8,433,448	3,397,169
Total operating expenses	10,031,948	8,184,795	18,665,814	6,151,135
Operating loss	(10,031,948)	(8,184,795)	(18,665,814)	(6,151,135)
Other income (expense)				
Change in fair value of derivative liabilities	—	—	—	(867,000)
Change in fair value of warranty liability	—	—	—	(6,109)
Grant income	868,345	41,720	1,080,436	278,333
Loss on sale of equipment	—	—	—	(3,082)
Interest expense	—	—	—	(95,070)
Interest income	5,017	1,773	20,410	664
Total other income (expense)	873,362	43,493	1,100,846	(692,264)
Loss before income taxes	(9,158,586)	(8,141,302)	(17,564,968)	(6,843,399)
Income tax expense (benefit)	—	—	—	—
Net loss	\$ (9,158,586)	\$ (8,141,302)	\$ (17,564,968)	\$ (6,843,399)
Basic and diluted loss per common share(1)	\$ (8.97)	\$ (12.55)	\$ (27.07)	\$ (16.24)
Weighted average number of common shares outstanding, basic and diluted(1)	1,020,644	648,862	648,861	421,294
Balance Sheet Data				
Cash	\$3,572,475	\$4,968,418	\$20,825,860	
Current assets	4,892,937	7,379,405	22,732,175	
Total assets	5,881,545	7,587,986	22,938,443	
Current liabilities	3,523,430	4,347,290	2,534,097	
Total liabilities	3,789,082	4,347,290	2,534,097	
Total stockholders' equity	2,092,463	3,240,696	20,404,346	
¹⁾ See note 13 to our audited financial statements and our unaudited interim financial statements for further details on the calculation of basic and diluted net loss per common share.				

Risk Factors

Investing in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below, and the risk factors included in our [Annual Report on Form 10-K filed with the SEC on March 31, 2023](#), and the most recent [Form 10-Q filed with the SEC on August 14, 2023](#) incorporated by reference into this prospectus, as well as the other information in this prospectus and the documents incorporated by reference into this prospectus. 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, prospects, 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” incorporated by reference into this prospectus. The trading price of our common stock could decline significantly due to any of these risks or other factors, 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 identified conditions and events that raise substantial doubt about our ability to continue operations in the near-term. We may need to seek an in-court or out-of-court restructuring of our liabilities.

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

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

As initially disclosed on our Current Report on Form 8-K filed with the SEC on May 18, 2023, we received a letter from the Listing Qualifications Department (the “Staff”) of The Nasdaq Stock Market LLC (“Nasdaq”) on May 16, 2023, that we are not in compliance with the stockholders’ equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) requires that companies listed on the Nasdaq Capital Market maintain stockholders’ equity of at least \$2,500,000 (the “Stockholders’ Equity Requirement”) or that they meet one of the alternative listing standards, market value of listed securities of at least \$35 million or net income of \$500,000 from continuing operations in the most recently completed fiscal year, or in two of the three most recently completed fiscal years. We were given 45 calendar days, or until June 30, 2023, to submit a plan to Nasdaq describing how we intend to seek to regain compliance with the Stockholders’ Equity Requirement (the “Compliance Plan”).

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

On July 26, 2023, the Company received a Delisting Determination Letter from the Staff advising the Company that the Staff had determined not to accept the Company’s Compliance Plan, that the Company’s request for an extension had been denied, and that the Company’s common stock was subject to delisting

Risk Factors

from the Nasdaq Capital Market (the “Delisting Determination”). In accordance with Nasdaq Listing Rule 5815(a)(2), the Company was provided with seven calendar days, or until August 2, 2023, to request a hearing before the Nasdaq Hearings Panel (the “Panel”) to appeal the Delisting Determination. The Company submitted a request for a hearing to Nasdaq, and on August 2, 2023, was notified by Nasdaq that an oral hearing (the “Hearing”) by the Panel to discuss the Delisting Determination has been scheduled for October 2023. Accordingly, any delisting action by the Staff will be stayed at least until the Hearing has been held and a final written decision by the Panel has been issued, and until any extension granted by the Panel following the Hearing expires.

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

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

Even if we consummate this offering, 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 therapeutic candidate development programs or commercialization efforts.

The development of pharmaceutical drugs is capital intensive. We are currently advancing TTX-MC138 into clinical development. Our current cash resources are insufficient to fund our planned operations or development plans beyond September 2023. We may not be able to complete our planned FIH trial, we may only be able to complete the trial in a small subset of patients and in only one tumor type. Even if completed, we will 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 therapeutic candidates or even to continue operations, either of which occurrence would have a material adverse effect on us.

We expect our expenses to continue 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 therapeutic candidates. In addition, if we obtain marketing approval for any of our current or future therapeutic candidates, we expect to incur significant commercialization expenses related to sales, marketing, 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 therapeutic candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we expect to continue to incur significant 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 therapeutic candidates, delay our pursuit of potential licenses or acquisitions, or significantly reduce our operations.

We expect that the net proceeds from this offering, together with our existing cash, will be sufficient to fund our operations to the end of 2023. 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 therapeutic candidates;

Risk Factors

- 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 therapeutic 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 license other current or future therapeutic 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 therapeutic candidates.

Identifying potential current or future therapeutic 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 therapeutic 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 therapeutic candidates. Disruptions in the financial markets in general, and those due to the COVID-19 pandemic in particular, 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 could result in 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 therapeutic 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 therapeutic 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.

Risks related to our securities and this offering

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.

Trading volume in shares of our common stock on the Nasdaq Capital Market has been limited. 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.

Risk Factors

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 in this offering.

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 in this offering.

Our stock price has been volatile since our initial public offering. 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, for numerous reasons including as a result of the COVID-19 pandemic, economic events and expectations, and the war in the Ukraine. 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 in this offering or otherwise. 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 therapeutic 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 therapeutic candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or license additional current or future therapeutic 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 and in the documents incorporated by reference herein.

If the market price of our common stock after this offering does not exceed the public offering price in this offering, you may not realize any return on your investment in us and you may lose some or all of your investment. Additionally, 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.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from the offering, including for any of the purposes described in “Use of Proceeds.” You will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used effectively. Because of the number and variability of factors that will determine our use of the net proceeds, their ultimate use may differ substantially

Risk Factors

from what we currently intend. The failure by our management to apply these funds effectively could adversely affect us. Pending their use, we may invest the net proceeds in short-term, investment-grade, interest-bearing securities or commercial bank accounts. While we intend to invest the net proceeds conservatively, there is no assurance that these investments will not decline in value or yield reasonable returns.

If you purchase our securities in this offering, you will incur immediate and substantial dilution in the book value of your shares of common stock.

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the assumed public offering price of \$ per share, the last reported price of our common stock on the Nasdaq Capital Market on , 2023, purchasers of securities in this offering will experience immediate dilution of \$ per share in net tangible book value of the common stock. See the section of this prospectus titled “*Dilution*” for a more detailed description of these factors.

There is no public market for any pre-funded warrants sold in this offering.

There is no established public trading market for the pre-funded warrants being sold in this offering. We will not list the pre-funded warrants on any securities exchange or nationally recognized trading system, including the Nasdaq Capital Market. Therefore, we do not expect a market to ever develop for the pre-funded warrants. Without an active market, the liquidity of the pre-funded warrants will be limited.

The pre-funded warrants are speculative in nature.

The pre-funded warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but merely represent the right to acquire shares of common stock at a fixed price. Commencing on the date of issuance, holders of pre-funded warrants may exercise their right to acquire the underlying common stock and pay the stated warrant exercise price per share.

Until holders of pre-funded warrants acquire shares of our common stock upon exercise thereof, holders of such pre-funded warrants will have no rights with respect to shares of our common stock. Upon exercise of the pre-funded warrants, such holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or current or future therapeutic 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 therapeutic 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 therapeutic candidates, delay our pursuit of potential licenses or acquisitions, or grant rights to develop and market current or future therapeutic candidates that we would otherwise prefer to develop and market ourselves.

Risk Factors

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

The holdings of our executive officers, directors, principal stockholders and their affiliates represent beneficial ownership, in the aggregate, of 250,876 shares of our outstanding common stock as of August 24, 2023, representing approximately 12.4% of our total shares of common stock outstanding as of such date, or approximately % of our outstanding common stock after giving effect to the assumed sale of shares of common stock in this offering. The foregoing calculation assumes no exercise of the underwriter's overallotment option, no sales of pre-funded warrants in this offering and no exercise of options and warrants outstanding as of the date of this prospectus. If the specified individuals exercised all options they hold, and no other options were exercised by any other holder, the holdings of the specified individuals would represent beneficial ownership, in the aggregate, of approximately 19.0% of our outstanding common stock prior to this offering, or approximately % of our outstanding common stock after giving effect to the assumed sale of shares of common stock in this offering, assuming no exercise of the underwriter's overallotment option, no sales of pre-funded warrants in this offering and no exercise of options and warrants outstanding as of the date of this prospectus. As a result of their combined ownership, these stockholders, if they act together, may 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 certain of their shares of common stock for substantially less than the price of the shares of common stock sold in our initial public offering and being sold in this offering, and these stockholders may have interests, with respect to their common stock, that are different from those of investors who invest in this 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

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- 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 the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering (i.e., December 31, 2026), (b) in which we have total annual gross revenue of at least \$1.235 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 may be influenced, in part, on the research and reports that industry or financial analysts publish about us or our business. If begun, we may lose research coverage by industry or financial analysts. If no or few analysts maintain coverage of us, the trading price of our stock would likely decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock would likely 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.

Risk Factors

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 are 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. In connection with the preparation of our financial statements as of and for the years ended December 31, 2022 and 2021, 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, 2022 and 2021, 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, implementation of these and other 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

Risk Factors

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 following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier. 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 States 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.

Risk Factors

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.

Cautionary Note Regarding Forward-Looking Statements

This prospectus 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 Exchange Act. 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 included in this prospectus for purposes of complying with those safe harbor provisions. All statements other than statements of historical facts contained in this prospectus and our other public filings 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 clinical development and trials, regulatory review and approvals, our results of operations and financial condition, liquidity, prospects, growth, strategies and the industry in which we operate. These forward-looking statements are subject to known and unknown risks and uncertainties, assumptions and other factors that could cause our actual results to differ materially from those expressed in, or implied by, these forward-looking statements. Factors that could cause these differences include, but are not limited to:

- > our immediate low cash position, our estimates and expectations regarding our capital requirements, cash and expense levels, liquidity sources and our ability to obtain, on satisfactory terms or at all, the financing required to support operations, research, development, clinical trials, and commercialization of products;
- > a potential delisting of our common stock from trading on the Nasdaq Capital Market;
- > the results and timing of our preclinical and clinical trial activities;
- > our ability to expand our therapeutic candidate portfolio through internal research and development or the acquisition or in-licensing of intellectual property assets;
- > the impact of the global outbreak of the COVID-19 coronavirus, including the spread of new strains of the virus, on our activities as above-described and otherwise, including but not limited to our ability to enroll a sufficient number of patients to advance the above-described clinical trials;
- > the results and timing of our preclinical and clinical trial activities;
- > the therapeutic benefits, effectiveness and safety of our therapeutic candidates;
- > our ability to receive regulatory approval for our therapeutic candidates in the United States, Europe and other geographies;
- > the expected regulatory approval pathway for our therapeutic candidates;
- > potential changes in regulatory requirements, and delays or negative outcomes from the regulatory approval process;
- > our reliance on third parties for the planning, conduct and monitoring of clinical trials, for the manufacture of clinical drug supplies and drug product and for other requirements;
- > our ability to expand our therapeutic candidate portfolio through internal research and development or the acquisition or in-licensing of intellectual property assets;
- > our estimates of the size and characteristics of the markets that may be addressed by our therapeutic candidates;
- > market acceptance of our therapeutic candidates that are approved for marketing in the United States or other countries;
- > our ability to successfully commercialize our therapeutic candidates;
- > the safety and efficacy of therapeutics marketed by our competitors that are targeted to indications which our therapeutic candidates have been developed to treat;

Cautionary Note Regarding Forward-Looking Statements

- the impact of natural disasters, global pandemics (including further outbreaks of existing strains of COVID-19 or new strains of the virus), labor disputes, lack of raw materials or other supplies, issues with facilities and equipment or other forms of disruption to business operations at our manufacturing or laboratory facilities or those of our vendors, or at clinical trial sites;
- our ability to utilize our proprietary technological approach to develop and commercialize our therapeutic candidates;
- our heavy dependence on licensed intellectual property, including our ability to source and maintain licenses from third-party owners;
- our ability to protect our intellectual property and operate our business without infringing the intellectual property rights of others;
- our ability to attract, retain and motivate key personnel;
- our ability to generate revenue and become profitable;
- our reliance on third-party manufacturers to manufacture our drug substance and drug product that meets with our design specifications;
- our dependence on contract research organizations and other institutions to manage our clinical trials;
- other risks and uncertainties, including those listed under the caption “Risk Factors” in our Annual Report on Form 10-K and in our other regulatory filings, including our Quarterly Report on Form 10-Q filed with the SEC on August 14, 2023.

The risks set forth above are not exhaustive. Other sections of this prospectus 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 contained in this prospectus 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. 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.

Industry and Other Data

This prospectus may include industry, market, competitive position and other data. We obtain such information from industry publications and research, surveys and studies conducted by third-parties. 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 prospectus also may include data based on our own internal estimates and research. Our internal estimates have not been verified by any independent source. While we believe any data obtained from industry publications and third-party research, surveys and studies and our own estimates are reliable, we have not independently verified such data. The industry in which we operate, as well as such third-party data and our internal estimates and research, are subject to a high degree of uncertainty and risks due to a variety of factors, including those described in “*Risk Factors*” elsewhere in this prospectus and our other public filings. These and other factors could cause our results to differ materially from those expressed in this prospectus and our other public filings.

Use of Proceeds

We estimate that the net proceeds we will receive from the sale of our common stock in this offering, after deducting underwriter discounts and commissions and other offering expenses payable by us and assuming no sale of any pre-funded warrants, will be approximately \$ million (or \$ million if the underwriter exercises its option to purchase additional shares in full), based on an assumed public offering price of \$ per share and pre-funded warrants, which was the last reported sale price of our common stock on the Nasdaq Capital Market on , 2023.

We currently expect to use the net proceeds from this offering, together with our existing funds, for product development activities, including one or more clinical trials with TTX-MC138, our lead therapeutic candidate, including related IND enabling studies, and for working capital and other general corporate purposes.

From time to time in the ordinary course of our business, we may evaluate the acquisition of, investment in or in-licensing of additional therapeutic candidates that we believe are commercially viable or to develop ourselves. We could use a portion of the net proceeds from this offering for such purposes. We may also use a portion of the net proceeds of this offering for the acquisition or licensing of additional technologies, other assets or businesses, or for other strategic investments or opportunities, although we currently have no understandings, agreements or commitments with respect to any of the foregoing.

Although we currently anticipate that we will use the net proceeds from this offering as described above, there may be circumstances where we determine that a different use of our funds is in the best interest of the company. The amounts and timing of our actual expenditures will depend upon numerous factors, including results and progress of our clinical trial activities, results of and progress of our preclinical development activities, the progress of any partnering efforts we conduct, our operating costs, technological advances, the competitive environment for our therapeutic candidates and other factors described in the section titled “*Risk Factors*” in this prospectus. Our management will have flexibility in applying the net proceeds from this offering and you will be relying on their judgment with regard to the use of these net proceeds. An investor purchasing shares of our common stock will not have the opportunity, as part of the investment decision, to evaluate the economic, financial or other information on which we base our decisions about how to use the proceeds or to make their own assessment of whether the proceeds are being used appropriately. It is possible that the net proceeds will be used in a way that does not yield a favorable, or any, return for us.

A \$1.00 increase (decrease) in the assumed public offering price per share set forth above would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming the number of shares and pre-funded warrants offered by us, as set forth on the cover of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated expenses payable by us. An increase (decrease) of one million shares (or pre-funded warrants) sold by us in this offering would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming the public offering price per share remains the same and after deducting underwriting discounts and commissions and estimated expenses payable by us. The information in this paragraph is illustrative only and will change based on the actual public offering price and other terms of this offering determined at the pricing of this offering.

We believe that the net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses and capital expenditure requirements to the end of 2023. They are not expected to be sufficient to fund advancement of any of our therapeutic candidates through regulatory approval. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We will need to raise substantial additional funds to complete development and commercialization of our therapeutic candidates which development or commercialization may not be successful.

Pending our use of the net proceeds from this offering as described above, we intend to invest the net proceeds in investment grade interest bearing instruments or will hold the proceeds in interest bearing or non- interest-bearing accounts in U.S. banks.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, for development and expansion of our business. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors deems relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Capitalization

The following unaudited table sets forth our cash and our capitalization at June 30, 2023:

- > on an actual basis; and
- > on an as adjusted basis to give effect to the sale and issuance by us of _____ shares of our common stock in this offering, at an assumed offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Capital Market on _____, 2023, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the following table together with the sections of this prospectus titled “*Summary Financial Data*,” as well as our financial statements and the related notes, and “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” incorporated herein by reference to our Form 10-K filed with the SEC on March 31, 2023, and our Form 10-Q for the quarter ended June 30, 2023, filed with the SEC on August 14, 2023.

	June 30, 2023	
	(unaudited)	
	Actual	As Adjusted
Cash	\$ 3,572,475	\$ _____
Stockholders’ equity		
Preferred stock – \$0.0001 par value; 10,000,000 shares authorized actual and as adjusted; no shares issued or outstanding actual or as adjusted	—	—
Common stock – \$0.0001 par value; 290,000,000 shares authorized; 1,950,674 shares issued and outstanding actual; shares issued and outstanding as adjusted	\$ 195	\$ _____
Additional paid-in capital	39,121,104	
Accumulated deficit	(37,028,836)	
Total stockholders’ equity	\$ 2,092,463	\$ _____
Total capitalization	\$ 2,092,463	\$ _____

The number of shares of common stock to be outstanding after the offering is based on 1,950,674 shares of common stock outstanding as of June 30, 2023, and excludes, as of that date, the following:

- > 267,277 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of \$10.84 per share;
- > 15,625 shares of common stock issuable upon the exercise of outstanding IPO Underwriter Warrants at an exercise price of \$100.00 per share;
- > 9,962 shares of common stock issuable upon exercise of outstanding February 2023 Placement Agent Warrants at an exercise price of \$13.18 per share;
- > 6,250 shares of common stock issuable upon exercise of outstanding Consultant Warrants at an exercise price of \$10.00 per share;
- > 950,000 shares of common stock issuable upon the exercise of outstanding pre-funded warrants at an exercise price of \$0.01 per share;
- > 140,000 shares of common stock issuable upon the exercise of outstanding placement agent warrants at an exercise price of \$4.38 per share;
- > 2,000,000 shares of common stock issuable upon the exercise of outstanding Series A-1 warrants at an exercise price of \$3.25 per share;

Capitalization

- > 2,000,000 shares of common stock issuable upon the exercise of outstanding Series A-2 warrants at an exercise price of \$3.25 per share;
- > 4,479 shares of common stock reserved for future issuance under our 2021 Stock Option and Equity Incentive Plan, or the 2021 Plan; and
- > 16,500 shares of common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, or our 2021 ESPP.

Except as otherwise indicated herein, all information in this prospectus assumes the following:

- > no exercise by the underwriter of the over-allotment option to purchase additional shares (or pre-funded warrants in lieu thereof);
- > no exercise of outstanding options or warrants;
- > no exercise of the underwriter's warrants to be issued upon consummation of this offering at an exercise price equal to 125% of the initial offering price of the common stock; and
- > no sale of any pre-funded warrants.

Dilution

If you invest in our common stock in this offering, your ownership interest may be diluted immediately depending on the difference between the public offering price per share of our common stock (assuming no pre-funded warrants are sold in this offering) and the as adjusted net tangible book value per share of our common stock immediately after this offering (assuming no pre-funded warrants are sold in this offering).

At June 30, 2023, we had a net tangible book value of \$2,092,463 or \$1.03 per share. Net tangible book value per share represents our total tangible assets (total assets less intangible assets) less total liabilities at that date, divided by the total number of our outstanding shares of common stock as of August 24, 2023.

After giving effect to the sale and issuance of _____ shares of common stock in this offering, assuming no exercise of the over-allotment option, at an assumed public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Capital Market on _____, 2023, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2023, would have been approximately \$ _____ million, or \$ _____ per share of our common stock (assuming no pre-funded warrants are sold in this offering). This represents an immediate increase in net tangible book value of approximately \$ _____ per share to our existing stockholders and immediate dilution of \$ _____ per share to new investors.

The dilutive or antidilutive effect per share to investors participating in this offering is determined by subtracting the as adjusted net tangible book value per share after this offering from the public offering price per share paid by investors participating in this offering. The following table illustrates this result (without giving effect to any exercise by the underwriter of its option to purchase additional shares) on a per share basis:

Assumed public offering price per share	\$
Net tangible book value per share at June 30, 2023	\$ 1.03
Increase in book value per share attributable to new investors	\$
As adjusted net tangible book value per share after this offering	\$
Dilution per share to new investors	\$

An increase or decrease of \$1.00 in the assumed public offering price of \$ _____ per share, which is the last reported trading price of our common stock on the Nasdaq Capital Market on _____, 2023, would increase or decrease our as adjusted net tangible book value per share after this offering by \$ _____ and dilution per share to new investors purchasing shares in this offering by \$ _____, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

An increase of one million shares in the number of shares offered by us in this offering would change the as adjusted net tangible book value per share to \$ _____. A decrease of one-million shares in the number of shares offered by us in this offering would increase the as adjusted net tangible-book value per share to \$ _____, resulting in immediate dilution to investors participating in this offering. The foregoing calculations assume that the public offering price remains the same, and are after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

If the underwriter's over-allotment option is exercised in full, our as adjusted net tangible book value per share after this offering would be approximately \$ _____ million and there would be no additional dilutive or antidilutive effect per share to new investors purchasing common stock in this offering. These calculations assume a public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Capital Market on _____, 2023, and are after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Dilution

The table and discussion above are based on 1,950,674 shares of common stock outstanding at June 30, 2023, assume no sale of any pre-funded warrants, and exclude, as of that date, the following:

- > 267,277 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of \$10.84 per share;
- > 15,625 shares of common stock issuable upon the exercise of outstanding IPO Underwriter Warrants at an exercise price of \$100.00 per share;
- > 9,962 shares of common stock issuable upon exercise of outstanding February 2023 Placement Agent Warrants at an exercise price of \$13.18 per share;
- > 6,250 shares of common stock issuable upon exercise of outstanding Consultant Warrants at an exercise price of \$10.00 per share;
- > 950,000 shares of common stock issuable upon the exercise of outstanding pre-funded warrants at an exercise price of \$0.01 per share;
- > 140,000 shares of common stock issuable upon the exercise of outstanding placement agent warrants at an exercise price of \$4.38 per share;
- > 2,000,000 shares of common stock issuable upon the exercise of outstanding Series A-1 warrants at an exercise price of \$3.25 per share;
- > 2,000,000 shares of common stock issuable upon the exercise of outstanding Series A-2 warrants at an exercise price of \$3.25 per share;
- > 4,479 shares of common stock reserved for future issuance under our 2021 Stock Option and Equity Incentive Plan, or the 2021 Plan; and
- > 16,500 shares of common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, or our 2021 ESPP.

To the extent that outstanding options or warrants are exercised, or shares are issued under our equity incentive plans, you may experience dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that, in the future, additional capital is raised through the sale of equity, convertible debt securities, or securities with equity components, those issuances may result in dilution to our stockholders.

Description of Capital Stock and Securities we are Offering

General

The following description summarizes important terms of our capital stock, the rights of such stock, certain provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws, certain provisions of Delaware General Corporation Law, and the pre-funded warrants. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Amended and Restated Certificate of Incorporation, as amended, our Amended and Restated Bylaws, and applicable provisions of the Delaware General Corporation Law.

Capital Stock

Our authorized capital stock consists of 290 million shares of common stock, par value \$0.0001 per share, and 10 million shares of preferred stock, par value \$0.0001 per share, all of which shares of preferred stock are undesignated. As of August 24, 2023, 2,025,674 shares of our common stock were outstanding, reflecting the exercise of 75,000 pre-funded warrants subsequent to June 30, 2023, held by approximately 18 stockholders of record. As of August 24, 2023, there were no shares of preferred stock outstanding.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of our stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding convertible preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding convertible preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 10 million shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments if we liquidate. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. As of August 24, 2023, there were no shares of preferred stock outstanding.

Stock Options

In April 2020, the company adopted the 2020 Stock Option and Incentive Plan, or the 2020 Plan, which provided for awards to purchase up to 151,639 shares of our common stock. In March 2021, the company adopted its 2021 Stock Option and Incentive Plan, or the 2021 Plan, which provided for awards to purchase up to 125,000 shares of our common stock plus annual increases in such number of shares, and, with the 2020 Plan, the Plans. The purpose of the Plans is to encourage and enable our officers, employees, directors, consultants and other key persons (including prospective employees, but conditioned on their employment)

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upon whose judgment, initiative and efforts the company largely depends for the successful conduct of its business, to acquire a proprietary interest in the company. Upon completion of our initial public offering, or our IPO, our Board of Directors determined that no further awards under the 2020 Plan would be made. At that time, there were 89,632 shares subject to options outstanding under the 2020 Plan.

As of June 30, 2023, options to purchase an aggregate of 267,277 shares of our common stock were outstanding under the Plans, of which 85,198 were exercisable.

Warrants

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

Description	Number of Shares	Exercise Price Per Share
IPO Underwriter Warrants	15,625	\$100.00
February 2023 Placement Agent Warrants	9,962	13.18
Consultant Warrants	6,250	10.00
Series A-1 Warrants	2,000,000	3.25
Series A-2 Warrants	2,000,000	3.25
June 2023 Placement Agent Warrants	140,000	4.38
June 2023 Pre-funded Warrants	950,000	0.01

Upon the closing of our IPO, we issued as compensation to the underwriter warrants, or the IPO Underwriter Warrants, to purchase up to 15,625 shares of common stock exercisable at \$100.00 per share. The IPO Underwriter Warrants are exercisable at any time and from time to time, in whole or in part, until July 8, 2026.

Upon the closing of our registered direct offering on February 17, 2023, we issued as compensation to the placement agent warrants, or the February 2023 Placement Agent Warrants, to purchase up to 9,962 shares of common stock exercisable at \$13.18 per share. The February 2023 Placement Agent Warrants are exercisable beginning six months after the closing of the offering and expire five years after issuance.

In connection with an agreement we entered into with a consultant, we agreed to issue warrants, or the Consultant Warrants, to purchase up to 12,500 shares of common stock at \$10.00 per share. The Consultant Warrants are exercisable any time after six months from the effective date of the agreement (February 23, 2023) through the fifth anniversary thereof, subject to our right in our sole discretion exercisable not later than August 22, 2023, to reduce the number of warrants to 6,250. On May 31, 2023, we exercised this right.

Upon the closing of our registered direct offering on June 9, 2023 we issued pre-funded warrants, or the June 2023 Pre-funded Warrants, to purchase up to 1,901,000 shares of our common stock at an exercise price of \$0.01 per share. The June 2023 Pre-funded Warrants are exercisable immediately after the closing and have no expiration date. We also issued warrants, or the Series A-1 Warrants, to purchase up to 2,000,000 shares of our common stock at an exercise price of \$3.25 per share, and additional warrants, or the Series A-2 Warrants, to purchase up to 2,000,000 shares of our common stock at an exercise price of \$3.25 per share. The Series A-1 Warrants and the Series A-2 Warrants are exercisable at any time following closing and expire three years following the date of sale and have an exercise price of \$3.25 per share. In addition, we also issued as compensation to the placement agent warrants, or the June 2023 Placement Agent Warrants, to purchase up to 140,000 shares of common stock at an exercise price of \$4.375 per share. The June 2023 Placement Agent Warrants are exercisable at any time following the date of issuance, and expire three years following the closing date.

In addition, in this offering, we have agreed to issue as compensation to the underwriter warrants to purchase up to () if the underwriter exercises its over-allotment option in full) shares of common stock (5% of the aggregate number of shares of common stock sold in this offering). The underwriter's warrants will

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be exercisable at a per share exercise price equal to 125% of the public offering price per share in this offering. The underwriter's warrants are exercisable at any time and from time to time, in whole or in part, during the four and one-half year period commencing 180 days from the effective date of the registration statement of which this prospectus is a part.

Pre-Funded Warrants

The following is a summary of certain terms and provisions of the pre-funded warrants offered hereby in lieu of shares of common stock. This summary is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price. Each pre-funded warrant offered hereby will have an initial exercise price per share equal to \$0.01. The pre-funded warrants will be immediately exercisable and may be exercised at any time. There is no expiration date for the pre-funded warrants. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

Exercisability. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% (or at the election of the holder prior to the issuance of any pre-funded warrants, 9.99%) of the outstanding shares of common stock immediately after exercise. Any holder may increase such percentage to any percentage not in excess of 9.99% upon at least 61 days' prior notice to us. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares of common stock, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price of such pre-funded warrant or round up to the next whole share.

Cashless Exercise. In lieu of making the cash payment of the aggregate exercise price otherwise contemplated to be made to us upon such exercise, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Fundamental Transaction. In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding shares of common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding shares of common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

Transferability. Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

No Exchange Listing. We do not intend to list the pre-funded warrants on any securities exchange or nationally recognized trading system.

No Rights as a Stockholder. Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights.

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Anti-Takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our certificate of incorporation provides that directors may be removed only for cause and then only by the affirmative vote of the holders of at least two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The limitations on removal of directors and treatment of vacancies have the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws will limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment,

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voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our certificate of incorporation provides for 10 million authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of Forum

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 States 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 business address is in Boston, Massachusetts. These forum provisions may impose additional costs on stockholders, may limit our stockholders' ability to bring a claim in a forum they find favorable, and the designated courts may reach different judgments or results than other courts. In addition, there is uncertainty as to whether the Federal Forum Provision will be enforced, which may impose additional costs on us and stockholders.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under

Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

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- > upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- > at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- > any merger or consolidation involving the corporation and the interested stockholder;
- > any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- > subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- > subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- > the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Market Listing

Our common stock is traded on the Nasdaq Capital Market under the trading symbol "RNAZ." See "Risk Factors" on page 19 under the caption "*We could lose our listing on the Nasdaq Capital Market if we do not increase our stockholders' equity. The loss of our Nasdaq listing would in all likelihood make our common stock significantly less liquid and adversely affect its value.*"

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer, LLC.

Material U.S. Federal Income Tax Considerations

The following discussion is a summary of certain material U.S. federal income tax consequences of (i) the purchase, ownership and disposition of shares of our common stock issued pursuant to this offering, or the Shares and (ii) the purchase, ownership and disposition of the pre-funded warrants. The Shares and pre-funded warrants are referred to collectively herein as our securities. This summary does not purport to be a complete analysis of all potential tax consequences relating to the purchase, ownership, exercise, lapse and disposition of our securities. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable U.S. state or local or non-U.S. tax laws are not discussed, nor is the potential application of the alternative minimum tax, the Medicare contribution tax on net investment income, or the special tax accounting rules under Section 451(b) of the U.S. Internal Revenue Code of 1986, as amended, or the Code. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, exercise, lapse and disposition (as applicable) of our securities.

This discussion is limited to holders that hold our securities as “capital assets” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a holder’s particular circumstances. In addition, it does not address consequences relevant to holders subject to special rules, including, without limitation:

- holders that own or are deemed to own more than 5% of our capital stock;
- certain former citizens or long-term residents of the United States;
- persons for whom shares of our common stock or pre-funded warrants constitute “qualified small business stock” within the meaning of Section 1202 of the Code;
- persons holding our securities as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- persons deemed to sell our securities under the constructive sale provisions of the Code;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities or currencies;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- S corporations, partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- tax-qualified retirement plans;
- holders who hold or receive our securities pursuant to the exercise of employee stock options or otherwise as compensation; and
- “qualified foreign pension funds” as defined in Section 897(1)(2) of the Code and entities all of the interests of which are held by one or more qualified foreign pension funds.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our securities, the tax treatment of a partner in such partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding securities and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

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THIS DISCUSSION IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP, EXERCISE, LAPSE AND DISPOSITION OF OUR SECURITIES ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY U.S. STATE OR LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, a pre-funded warrant should be treated as a share of our common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of such shares, as described below. Accordingly, no gain or loss should be recognized upon the exercise of a pre-funded warrant and, upon exercise, the holding period of a pre-funded warrant should carry over to the share received. Similarly, the tax basis of the pre-funded warrant should carry over to the share received upon exercise, increased by the exercise price of \$0.0001 per share. If a pre-funded warrant expires without being exercised, the holder should recognize a capital loss in an amount equal to such holder's tax basis in the pre-funded warrant. This loss will be long-term capital loss if, at the time of the expiration, the holder's holding period in the pre-funded warrant is more than one year. The deductibility of capital losses is subject to limitations.

Our characterization is not binding on the IRS, and the IRS may treat our pre-funded warrants as warrants to acquire shares of our common stock. In that case, the amount and character of your gain with respect to an investment in our pre-funded warrants could be materially different than the discussion set forth below. Accordingly, each holder should consult his, her or its tax advisor regarding the risks associated with the acquisition of pre-funded warrants pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that a pre-funded warrant is treated as a share of our common stock for U.S. federal income tax purposes.

Tax Considerations Applicable to U.S. Holders

Definition of U.S. Holder

In general, a "U.S. holder" means a beneficial owner of our securities (other than a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is, for U.S. federal income tax purposes:

- > an individual who is a citizen or resident of the United States;
- > a corporation, or an entity treated as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- > an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- > a trust if (a) a U.S. court can exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (b) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

Distributions on the Shares

As described in the section titled "Dividend Policy," we do not anticipate declaring any cash dividends to holders of common stock in the foreseeable future. However, if we do make distributions (including constructive distributions as described below) on our Shares, such distributions will constitute dividends to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, and will be includible in your income as ordinary income when received. However, with respect to dividends received by individuals, such dividends generally are taxed under current law at applicable

Material U.S. Federal Income Tax Considerations

long-term capital gains rates, provided certain holding period requirements are satisfied. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the U.S. holder's investment, up to such U.S. holder's adjusted tax basis in the Shares. Any remaining excess will be treated as capital gain from the sale or exchange of such Shares, as applicable, subject to the tax treatment described below in "— Sale or Other Taxable Disposition of Our Securities."

Constructive Dividends on Pre-Funded Warrants

Under Section 305 of the Code, an adjustment to (or failure to adjust) the number of shares that will be issued on the exercise of the pre-funded warrants, or an adjustment to (or failure to adjust) the exercise price of the pre-funded warrants, may be treated as a constructive distribution to a U.S. holder of the pre-funded warrants if, and to the extent that, such adjustment (or failure to adjust) has the effect of increasing such U.S. holder's proportionate interest in our assets or earnings and profits as determined under U.S. federal income tax principles, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). U.S. holders should consult their tax advisors as to (i) whether a constructive dividend deemed paid to a non-corporate U.S. holder would be eligible for the preferential rates of U.S. federal income tax applicable in respect of certain dividends received, (ii) whether corporate holders would be entitled to claim the dividends received deduction with respect to any such constructive dividends, and (iii) the general treatment of constructive distributions under their particular circumstances. Because a constructive dividend deemed received by a U.S. holder would not give rise to any cash from which any applicable withholding could be satisfied, if backup withholding is paid on behalf of a U.S. holder (because such U.S. holder failed to establish an exemption from backup withholding), such backup withholding may be set off against payments on the pre-funded warrants or Shares, or offset against other assets of such U.S. holder. Generally, a U.S. holder's adjusted tax basis in pre-funded warrant should be increased to the extent any such constructive distribution is treated as a dividend. U.S. holders should consult their tax advisors on the impact a constructive distribution may have on their holding period in the securities.

Sale or Other Taxable Disposition of Our Securities

Upon the sale, exchange or other taxable disposition of the Shares or pre-funded warrants, a U.S. holder will generally recognize capital gain or loss equal to the difference between the amount of cash and the fair market value of any property received upon the sale, exchange or other taxable disposition and such

U.S. holder's adjusted tax basis in such securities. This capital gain or loss will be long-term capital gain or loss if the U.S. holder's holding period in such securities is more than one year at the time of the sale, exchange or other taxable disposition. Long-term capital gains recognized by certain non-corporate U.S. holders, including individuals, generally will be subject to reduced rates of U.S. federal income tax. The deductibility of capital losses is subject to limitations.

Backup Withholding and Information Reporting

A U.S. holder may be subject to information reporting and backup withholding when such holder receives payments on our securities (including constructive dividends) or receives proceeds from the sale or other taxable disposition of our securities. Certain U.S. holders are exempt from backup withholding, including C corporations and certain tax-exempt organizations. A U.S. holder will be subject to backup withholding if such holder is not otherwise exempt and such holder:

- > fails to furnish the holder's taxpayer identification number, which for an individual is ordinarily his or her social security number;
- > furnishes an incorrect taxpayer identification number;
- > is notified by the IRS that the holder previously failed to properly report payments of interest or dividends; or
- > fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

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Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. U.S. holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Tax Considerations Applicable to Non-U.S. Holders

Definition of Non-U.S. Holder

For purposes of this discussion, a "non-U.S. holder" is a beneficial owner of our securities that is neither a U.S. holder (nor a partnership or an entity or arrangement treated as a partnership) for U.S. federal income tax purposes.

Distributions and Constructive Distributions

As described in the section titled "Dividend Policy," we do not anticipate declaring any cash dividends to holders of Common Stock in the foreseeable future. However, if we do make distributions of cash or property on the Shares, or if any deemed dividends result from certain adjustments, or failure to make adjustments, to the conversion rate or exercise price of the pre-funded warrants, as described above under "Tax Considerations Applicable to U.S. Holders — Constructive Dividends on Pre-Funded Warrants," such actual or deemed distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder's adjusted tax basis in its Shares or pre-funded warrants, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "— Sale or Other Taxable Disposition of Our Securities."

Subject to the discussion below on effectively connected income, backup withholding and FATCA, dividends paid or deemed paid to a non-U.S. holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the actual or deemed dividends (or such lower rate specified by an applicable income tax treaty, provided the non-U.S. holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). Because a constructive dividend deemed received by a non-U.S. holder would not give rise to any cash from which any applicable withholding tax could be satisfied, if withholding taxes are paid on behalf of a non-U.S. holder, those withholding taxes may be set off against payments of cash on the Shares or pre-funded warrants or sales proceeds received by or other funds or assets of such non-U.S. holder. A non-U.S. holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate of U.S. federal withholding tax, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaties.

If dividends paid or deemed paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such dividends are attributable), the non-U.S. holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the non-U.S. holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States. Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A non-U.S. holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

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Sale or Other Taxable Disposition of Our Securities

Subject to the discussions below regarding backup withholding and FATCA, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our securities unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);
- the non-U.S. holder is a nonresident alien individual present in the United States for a period or periods aggregating 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation", or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to United States persons (as defined in the Code). A non-U.S. holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by certain U.S. source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States), provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our worldwide real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or that we will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of the shares or common stock by a non-U.S. holder will not be subject to U.S. federal income tax if our common stock is (and assuming that our pre-funded warrants are not) "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such non-U.S. holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the non-U.S. holder's holding period. It is unclear how a non-U.S. holder's ownership of pre-funded warrants impacts the determination of the 5% threshold with respect to such non-U.S. holder's actual or constructive ownership of our common stock. There can be no assurance that our common stock will be or continue to be regularly traded on an established securities market. Our pre-funded warrants are not expected to be regularly traded on an established securities market. Dispositions by a non-U.S. holder of pre-funded warrants also may not be subject to U.S. federal income tax, even if we are treated as a U.S. real property holding corporation, if on the date such pre-funded warrants were acquired by such non-U.S. holder, such holdings had a fair market value no greater than the fair market value on that date of 5% of our common stock (if it is regularly traded on an established securities market), provided that, if such non-U.S. holder subsequently acquires additional pre-funded warrants, then such interests would be aggregated and valued as of the date of the subsequent acquisition to apply this 5% limitation.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of distributions on our securities (and constructive distributions deemed paid) will not be subject to backup withholding, provided the non-U.S. holder certifies its non-U.S. status, such as by furnishing a valid

Material U.S. Federal Income Tax Considerations

IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions paid or deemed paid to the non-U.S. holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our securities within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above or the non-U.S. holder otherwise establishes an exemption. Proceeds of a disposition of our common stock or pre-funded warrants conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on actual or deemed dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our securities paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of actual or deemed dividends on our securities. Proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds from the sale or other disposition of our securities. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our securities.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP, EXERCISE, LAPSE AND DISPOSITION OF OUR SECURITIES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

Underwriting

ThinkEquity is acting as the sole underwriter of this offering. We have entered into an underwriting agreement on [REDACTED], 2023, with respect to the offering of shares of our common stock. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase, at the public offering price less the underwriting discount set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Underwriter	Number of Shares	Number of Pre-Funded Warrants
ThinkEquity		
Total		

The underwriting agreement provides that the obligations of the underwriter to pay for and accept delivery of the shares of common stock and pre-funded warrants offered by this prospectus are subject to various conditions and representations and warranties, including the approval of certain legal matters by their counsel and other conditions specified in the underwriting agreement. The shares of common stock and pre-funded warrants are offered by the underwriter, subject to prior sale, when, as and if issued to and accepted by them.

We have agreed to indemnify the underwriter against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriter may be required to make in respect thereof.

Over-Allotment Option

We have granted a 45-day option to the underwriter to purchase up to an aggregate of [REDACTED] additional shares of our common stock and/or pre-funded warrants (equal to 15% of the common stock and pre-funded warrants sold in this offering) at the public offering price per share, less underwriting discounts and commissions, set forth on the cover page of this prospectus, solely to cover over-allotments, if any. If the underwriter exercises its option in whole or in part, then they will be committed, subject to the conditions described in the underwriting agreement, to purchase the additional shares of common stock.

Discounts, Commissions and Reimbursement

The underwriter has advised us that the underwriter proposes to offer the shares of common stock and pre-funded warrants to the public at the public offering price set forth on the cover page of this prospectus. The underwriter may offer shares and/or pre-funded warrants to dealers at that price less a concession not in excess of \$ [REDACTED] per share and/or pre-funded warrant, as applicable, of which up to \$ [REDACTED] per share and/or pre-funded warrant, as applicable, may be reallocated to other dealers. After the initial offering to the public, the underwriter may change the offering price and other selling terms.

The following table summarizes the underwriting discount and commissions and proceeds to us before deducting our other offering expenses. This information assumes either no exercise or full exercise of the over-allotment option we granted to the underwriter.

	Per Share	Per Pre-Funded Warrant	With No Over-Allotment	With Full Over-Allotment
Public offering price	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Underwriting discount (7.5%)	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Proceeds, before expenses, to us	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Non-accountable expense allowance (1%)	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]

Underwriting

We have paid \$50,000 to the underwriter as a deposit which will be applied against out-of-pocket accountable expenses of the underwriter in connection with this offering which we have agreed to pay. This deposit will be repaid to us to the extent not fully utilized. We have also agreed to pay a non-accountable expense allowance to the underwriter equal to 1% of the gross proceeds received at the closing of the offering. We have also agreed to pay certain expenses of the underwriter relating to this offering as set forth in the underwriting agreement, including the fees and expenses of the underwriter's legal counsel, in an amount not to exceed \$125,000.

We estimate that our total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts, commissions and reimbursements, will be approximately \$495,000

Underwriter's Warrants

Upon closing of this offering, we have agreed to issue warrants, or the underwriter's warrants, as additional compensation to the underwriter, providing for the purchase up to shares (if the over-allotment option is exercised in full) of our common stock (5% of the aggregate number of shares of common stock sold in the offering). The underwriter's warrants will be exercisable at a per share price equal to 125% of the public offering price per share in this offering. The underwriter's warrants are exercisable at any time and from time to time, in whole or in part, during the four and one-half year period commencing 180 days from the effective date of the registration statement of which this prospectus is a part.

The underwriter's warrants have been deemed compensation by the Financial Industry Regulatory Authority, or FINRA, and are therefore subject to a 180-day lock-up pursuant to FINRA Rule 5110(g)(1). The underwriter (or permitted assignees under Rule 5110(g)(1)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the effective date of the registration statement. In addition, the warrants provide for registration rights upon request in certain cases. The demand registration right provided will not be greater than five years from the effective date of the registration statement in compliance with FINRA Rule 5110(f)(2)(G)(iv) and is exercisable only one time by the underwriter. The piggyback registration right provided will not be greater than seven years from the effective date of the registration statement in compliance with FINRA Rule 5110(f)(2)(G)(v). We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants other than underwriting commissions incurred and payable by the selling holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a per share price below the warrant exercise price

Discretionary Accounts

The underwriter does not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority

Lock-Up Agreements

The company and our directors, officers and certain of our stockholders have agreed, subject to certain exceptions, for a period of three months with respect to the company (or two months if gross proceeds from this offering are less than \$10 million), and for a period of six months with respect to our directors, officers and certain of our stockholders, after the date of this prospectus, without the prior written consent of the underwriter, not to directly or indirectly:

- in the case of us, issue, offer, pledge, assign, encumber, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly,

Underwriting

- any shares of capital stock of the company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the company;
- > in the case of us, file or cause the filing of any registration statement under the Securities Act with respect to any shares of common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock;
- > complete any offering of debt securities of the company, other than entering into a line of credit, term loan arrangement or other debt instrument with a traditional bank;
- > enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the company's securities, whether any such transaction is to be settled by delivery of shares of our common stock or such other securities, in cash or otherwise;
- > sell, agree to sell, offer or sell, solicit offers to purchase, grant any call option, warrant or other right to purchase, purchase any put option or other right to sell, pledge, borrow or otherwise dispose of company's securities;
- > establish or increase any "put equivalent position" or liquidate or decrease any "call equivalent position" (in each case within the meaning of Section 16 of the Exchange Act) with respect to any company security;
- > make any demand for or exercise any right with respect to the registration of any company security;
- > otherwise enter into any swap, derivative or other transaction or arrangement that transfers to another, in whole or in part, any economic consequence of ownership of a company security, whether or not such transaction is to be settled by delivery of company securities, other securities, cash or other consideration; or
- > publicly announce an intention to do any of the foregoing.

Right of First Refusal

For the 12 months beginning February 18, 2024, we have granted the underwriter an irrevocable right of first refusal, in its sole discretion, to act as sole investment banker, sole book-runner, and/or sole placement agent, at the underwriter's sole discretion, for each and every future public and private equity and debt offering, including all equity-linked financings, of the company, or any successor to or any subsidiary of the company, on terms customary to the underwriter. The right of first refusal shall not apply to company transactions with strategic partners or other sources of non-dilutive funding, including government agencies and private foundations, or for which no broker-dealer is proposed to be engaged by the company. The underwriter will have the sole right to determine whether or not any other broker-dealer will have the right to participate in any such offering and the economic terms of any such participation. The underwriter will not have more than one opportunity to waive or terminate the right of first refusal in consideration of any payment or fee.

Market Listing

Our common stock is traded on the Nasdaq Capital Market under the symbol "RNAZ." There is no established trading market for the pre-funded warrants nor do we expect a market for such securities to develop. In addition, we do not intend to apply to list the pre-funded warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the pre-funded warrants will be limited.

Price Stabilization, Short Positions and Penalty Bids

In connection with this offering, the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchase to cover positions created by short sales. Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while this offering is in progress.

Underwriting

Over-allotment transactions involve sales by the underwriter of shares in excess of the number of shares the underwriter is obligated to purchase. This creates a syndicate short position in our common stock which may be either a covered short position or a “naked” short position. In a covered short position, the number of shares of common stock over-allotted by the underwriter is not greater than the number of shares of common stock that it may purchase through exercise of the over-allotment option. In a naked short position, the number of shares of common stock involved is greater than the number of shares common stock in the over-allotment option. To close out a syndicate short position, the underwriter may elect to exercise all or part of the over-allotment option. The underwriter may also elect to stabilize the price of our common stock or reduce any syndicate short position by bidding for, and purchasing, common stock in the open market.

Syndicate short covering transactions may involve purchases of shares in the open market after the distribution has been completed. In determining the source of shares to close out the short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which it may purchase shares through exercise of the over-allotment option. If the underwriter sells more shares than could be covered by exercise of the over-allotment option and, therefore, has a naked short position, the naked short position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in this offering.

The underwriter may also impose a penalty bid. Penalty bids permit an underwriter to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate-covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate short covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than the price that might otherwise exist absent these activities. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected in the over-the-counter market and otherwise and, if commenced, may be discontinued at any time.

Other Relationships

From time to time, the underwriter and/or its affiliates may in the future provide investment banking, commercial banking and other various financial services for us for which they may receive customary fees. In the course of their businesses, the underwriter and its affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the underwriter and its affiliates may at any time hold long or short positions in such securities or loans. Except for services provided in connection with this offering, no underwriter has provided any investment banking or other financial services to us during the 180-day period preceding the date of this prospectus and we do not expect to retain any underwriter to perform any investment banking or other financial services for at least 90 days after the date of this prospectus.

Indemnification

We have agreed to indemnify the underwriter against liabilities relating to this offering arising under the Securities Act and the Exchange Act, liabilities arising from breaches of some or all of the representations and warranties contained in the underwriting agreement, and to contribute to payments that the underwriter may be required to make for these liabilities.

Electronic Offer, Sale and Distribution of Securities

This prospectus in electronic format may be made available on websites or through other online services maintained by one or more of the underwriter or selling group members. The underwriter may agree to allocate a number of securities to selling group members for sale to their online brokerage account holders.
Internet

Underwriting

distributions will be allocated by the underwriter and selling group members making internet distributions on the same basis as other allocations. Other than this prospectus in electronic format, the information on the website of any underwriter or selling group member and any information contained in any other website maintained by an underwriter or selling group member is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Selling Restrictions

No action has been taken in any jurisdiction (except in the United States) that would permit a public offering of our common stock or the possession, circulation or distribution of this prospectus or any other material relating to us or our common stock in any jurisdiction where action for that purpose is required. Accordingly, our common stock may not be offered or sold, directly or indirectly, and this prospectus or any other offering material or advertisements in connection with our common stock may not be distributed or published, in or from any country or jurisdiction except in compliance with applicable rules and regulations of any such country or jurisdiction.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each a “Relevant Member State,” with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the “Relevant Implementation Date,” our securities will not be offered to the public in that Relevant Member State prior to the publication of a prospectus related to those securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of our securities may be made to the public in that Relevant Member State at any time:

- to any legal entity that is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriter for any such offer; or
- in any other circumstances which do not require the publication by the issuer of a prospectus pursuant to Article 3(2) of the Prospectus Directive, provided that no such offer of the securities shall require the issuer or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer of securities to the public” in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and securities to be offered so as to enable an investor to decide to purchase or subscribe for securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, and the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

United Kingdom

In the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the

Underwriting

Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together, the relevant persons). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates may be made or taken exclusively by relevant persons.

Canada

The offering of our common stock in Canada is being made on a private placement basis in reliance on exemptions from the prospectus requirements under the securities laws of each applicable Canadian province and territory where our common stock may be offered and sold, and therein may only be made with investors that are purchasing, or deemed to be purchasing, as principal and that qualify as both an “accredited investor” as such term is defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario) and as a “permitted client” as such term is defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any offer and sale of our common stock in any province or territory of Canada may only be made through a dealer that is properly registered under the securities legislation of the applicable province or territory wherein our common stock is offered and/or sold or, alternatively, where such registration is not required.

Any resale of our common stock by an investor resident in Canada must be made in accordance with applicable Canadian securities laws, which require resales be made in accordance with an exemption from, or in a transaction not subject to, prospectus requirements under applicable Canadian securities laws. These resale restrictions may under certain circumstances apply to resales of the common stock outside of Canada.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment hereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (“NI 33-105”), the underwriter is not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Upon receipt of this prospectus, each Québec investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur québécois confirme par les présentes qu’il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d’achat ou tout avis) soient rédigés en anglais seulement.*

Legal Matters

The validity of the securities offered by this prospectus will be passed upon for us by Goodwin Procter LLP. Certain legal matters will be passed upon for the underwriter by McGuireWoods LLP.

Experts

Our financial statements as of and for the years ended December 31, 2022 and 2021, included in our Annual Report on Form 10-K have been audited by Withum Smith+Brown, PC, independent registered public accounting firm, as stated in their report incorporated herein by reference (which report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern). Such financial statements have been so included in reliance upon the authority of said firm as experts in accounting and auditing.

Up to **Shares of Common Stock**
Pre-Funded Warrants to Purchase Shares of Common Stock

T R A N S C O D E
T H E R A P E U T I C S TM

TransCode Therapeutics, Inc.

PRELIMINARY PROSPECTUS

ThinkEquity

, 2023

Part II

Information not required in prospectus

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the fees and expenses, other than underwriting discounts, commissions and reimbursements, payable in connection with the registration of the securities hereunder. All amounts are estimates except the SEC registration fee and the FINRA filing fee.

	Amount paid or to be paid
SEC registration fee	\$ 1,346.51
FINRA filing fee	
Printing and mailing	
Legal fees and expenses	
Accounting fees and expenses	
Miscellaneous	
Total	<u>\$ 495,000</u>

Item 14. Indemnification of Directors and Officers.

Section 145 of the DGCL authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our amended and restated certificate of incorporation and amended and restated bylaws to be in effect immediately prior to the completion of this offering that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for any breach of the director's duty of loyalty to us or our stockholders; any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law; any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and

Part II

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- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We intend to enter into indemnification agreements with each of our directors, executive officers, and other officers as determined from time to time by our board of directors or our remuneration committee. These agreements will provide that we will indemnify each of our directors, officers with whom we have entered into indemnification agreements, and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for certain actions or proceedings arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third-parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we will agree in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third-parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We will maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriter against certain liabilities under the Securities Act and the Securities Exchange Act of 1934.

Item 15. Recent Sales of Unregistered Securities.

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

- (a) Between May 2018 and May 2020, we sold \$2,240,000 of interest-bearing, unsecured convertible notes, or Notes, to nine investors. The interest rate on the Notes was 6% per annum. At the closing of our IPO on July 13, 2021, all of our outstanding convertible promissory notes plus accrued interest converted into 53,406 shares of our common stock.
- (b) In June and July 2020, we granted to our directors, officers, employees, consultants and other service providers stock options to purchase an aggregate of 76,592 shares of common stock upon the exercise of options under our 2020 Plan at exercise prices per share of approximately \$1.65 to \$1.81.
- (c) In December 2020, we granted to our independent directors stock options to purchase an aggregate of 3,639 shares of common stock upon the exercise of options under our 2020 Plan at an exercise price per share of \$78.15.
- (d) In January 2021, we granted to an independent director stock options to purchase an aggregate of 1,819 shares of common stock at an exercise price of \$78.15 per share pursuant to our 2020 Plan.
- (e) In February 2023, in connection with an agreement we entered into with a consultant, we agreed to issue warrants to purchase up to 12,500 shares of common stock at \$10.00 per share. These warrants are exercisable any time after six months from the effective date of the agreement (February 23, 2023) through the fifth anniversary thereof, subject to our right in our sole discretion exercisable not later than August 22, 2023, to reduce the number of warrants to 6,250. This right was exercised on May 31, 2023.

Part II

- (f) In February 2023, in connection with our registered direct offering, we issued as compensation to the placement agent warrants to purchase up to 9,962 shares of common stock exercisable at \$13.18 per share. These warrants are exercisable beginning six months after the closing of the offering and expire five years after issuance.

The issuances of certain of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

Item 16. Exhibits and financial statement schedules.

(a) Exhibits

The Exhibit Index set forth below is incorporated by reference in response to this Item.

Exhibit number	Description
1.1**	Form of Underwriting Agreement.
3.1	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)).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of TransCode Therapeutics, Inc. (Incorporated by Reference to Exhibit 1.1 to the Registrant's Quarterly Report on Form 10-Q, filed on August 14, 2023).
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)).
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, filed on April 8, 2021 (File No. 333-253599)).
4.2**	Form of Pre-funded Warrant.
4.3**	Form of Underwriter's Warrant.
4.4	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599)).
4.5	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on February 17, 2023 (File No. 001-40363)).
4.6	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on June 6, 2023 (File No. 333-272082)).
4.7	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.3 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on June 5, 2023 (File No. 333-272082)).
4.8	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.4 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on June 5, 2023 (File No. 333-272082)).
5.1**	Opinion of Goodwin Procter LLP.
10.1#	2020 Stock Option and Incentive Plan and form of award agreements thereunder (Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, filed on February 26, 2021 (File No. 333-253599)).
10.2#	2021 Stock Option and Incentive Plan and form of award agreements thereunder (Incorporated by reference to Exhibit 10.2 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599)).

Part II

Exhibit number	Description
10.3#	Senior Executive Cash Incentive Bonus Plan (Incorporated by reference to Exhibit 10.3 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599)).
10.4#	Form of Indemnification Agreement between the Registrant and each of its executive officers (Incorporated by reference to Exhibit 10.4 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599)).
10.5#	Form of Indemnification Agreement between the Registrant and each of its directors (Incorporated by reference to Exhibit 10.5 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599)).
10.6	Exclusive Patent License Agreement by and between TransCode Therapeutics, Inc. and The General Hospital Corporation, d/b/a Massachusetts General Hospital, dated as of October 26, 2018 (Incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, filed on February 26, 2021 (File No. 333-253599)).
10.7#	First Amendment to Exclusive Patent License Agreement by and between TransCode Therapeutics, Inc. and The General Hospital Corporation, d/b/a Massachusetts General Hospital, dated as of October 30, 2020 (Incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, filed on February 26, 2021 (File No. 333-253599)).
10.8#	2021 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599)).
10.9#	Employment Agreement, dated as of March 24, 2021, by and Between TransCode Therapeutics, Inc. and Robert Michael Dudley (Incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, filed on April 8, 2021 (File No. 333-253599)).
10.10#	Letter Agreement, dated as of March 24, 2021, by and Between TransCode Therapeutics, Inc. and Robert Michael Dudley (Incorporated by reference to Exhibit 10.10 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on April 8, 2021 (File No. 333-253599)).
10.11#	Employment Agreement, dated as of March 24, 2021, by and Between TransCode Therapeutics, Inc. and Thomas A. Fitzgerald (Incorporated by reference to Exhibit 10.11 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on April 8, 2021 (File No. 333-253599)).
10.12#	Letter Agreement, dated as of March 24, 2021, by and Between TransCode Therapeutics, Inc. and Thomas A. Fitzgerald (Incorporated by reference to Exhibit 10.12 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on April 8, 2021 (File No. 333-253599)).
10.13	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 17, 2023).
10.14	Common Stock Purchase Agreement, dated April 13, 2023, by and between TransCode Therapeutics, Inc. and White Lion Capital LLC (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 13, 2023).
10.15	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 8-K, filed on June 6, 2023 (File No. 001-40363)).
21.1*	List of Subsidiaries of the Registrant.
23.1*	Consent of Withum Smith+Brown, PC, independent registered public accounting firm.
23.2**	Consent of Goodwin Procter LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (included on signature page).
107*	Filing Fee Table.

Indicates a management contract or any compensatory plan, contract or arrangement.

* Filed herewith.

** To be filed by amendment.

(b) Financial Statements Schedules: None.

Part II

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

- (1) The undersigned Registrant will provide to the underwriter at the closing specified in the securities placement agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.
- (2) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (3) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Signatures

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Commonwealth of Massachusetts, on the 29th day of August, 2023.

TRANSCODE THERAPEUTICS, INC.

By: /s/ Robert Michael Dudley

Robert Michael Dudley
Chief Executive Officer

Power of attorney and signatures

Each individual whose signature appears below hereby constitutes and appoints each of Robert Michael Dudley and Thomas A. Fitzgerald, MBA as such person's true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement (or any Registration Statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement and Power of Attorney has been signed by the following person in the capacities and on the date indicated.

Name	Title	Date
/s/ Robert Michael Dudley Robert Michael Dudley	<i>Director and Chief Executive Officer (Principal Executive Officer)</i>	August 29, 2023
/s/ Thomas A. Fitzgerald Thomas A. Fitzgerald, MBA	<i>Director and Chief Financial Officer (Principal Financial and Accounting Officer)</i>	August 29, 2023
/s/ Philippe P. Calais, PhD Philippe P. Calais, PhD	<i>Director</i>	August 29, 2023
/s/ Erik Manting, PhD Erik Manting, PhD	<i>Director</i>	August 29, 2023
/s/ Magda Marquet, PhD Magda Marquet, PhD	<i>Director</i>	August 29, 2023

List of Subsidiaries

None

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Prospectus constituting a part of this Registration Statement on Form S-1, of our report dated March 31, 2023, which includes an explanatory paragraph relating to Transcode Therapeutics, Inc.'s ability to continue as a going concern, relating to the financial statements of Transcode Therapeutics, Inc., which is incorporated by reference in that Prospectus. We also consent to the reference to us under the caption "Experts" in the Prospectus.

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey
August 29, 2023

Calculation of Filing Fee Tables

Form S-1
(Form Type)**TransCode Therapeutics, Inc.**
(Exact Name of Registrant as Specified in its Charter)Table 1: Newly Registered Securities

	Security Type	Security Class	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price ⁽¹⁾⁽²⁾⁽⁷⁾	Fee Rate	Amount of Registration Fee
Fees to be Paid	Equity	Common Stock, \$0.0001 par value per share ⁽⁷⁾	457(o)	–	–	\$11,500,000	0.0001102	\$1,267.30
Fees to be Paid	Equity	Pre-funded warrants to purchase Common Stock, \$0.0001 par value per share ⁽⁴⁾⁽⁷⁾⁽⁸⁾	457(g)	–	–	–	–	–
Fees to be Paid	Equity	Common Stock, \$0.0001 par value per share underlying the Pre-funded warrants ⁽⁵⁾⁽⁷⁾⁽⁸⁾	Other	–	–	–	–	–
Fees to be Paid	Equity	Underwriter's Warrants to Purchase Common Stock, \$0.0001 par value per share ⁽³⁾⁽⁴⁾	457(g)	–	–	–	–	–
Fees to be Paid	Equity	Common Stock, \$0.0001 par value per share underlying the Underwriter's Warrants ⁽⁵⁾⁽⁶⁾	457(o)	–	–	\$718,750	0.0001102	\$79.21
Total Offering Amounts						\$12,218,750		\$1,346.51
Total Fees Previously Paid								\$0
Net Fee Due								\$1,346.51

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").
 - (2) Includes the aggregate offering price of additional shares that the underwriter has the option to purchase pursuant to its over-allotment option.
 - (3) We have agreed to issue to the underwriter warrants to purchase the number of shares of our common stock (the "Underwriter's Warrants") in the aggregate equal to five percent (5%) of the shares of our common stock to be issued and sold in this offering, including upon exercise the option to purchase additional securities.
 - (4) No registration fee is required pursuant to Rule 457(g) under the Securities Act.
 - (5) In addition to the common stock set forth in this table, pursuant to Rule 416 under the Securities Act, this registration statement also registers such indeterminate number of common stock as may become issuable upon exercise of the Underwriter's Warrants and pre-funded warrants.
 - (6) The Underwriter's Warrants are exercisable for a price per share equal to 125% of the public offering price in this offering. As estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g), the proposed maximum aggregate offering price of the Representative's Warrants is \$718,7500, which is equal to 125% of \$575,000 (5% of the proposed maximum aggregate offering price of \$11,500,000).
 - (7) The proposed maximum aggregate offering price of the common stock proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded warrants offered and sold in the offering, and as such the proposed maximum offering price of the common stock and pre-funded warrants (including the common stock issuable upon exercise of the pre-funded warrants) if any, is \$11,500,000.
 - (8) The registrant may issue pre-funded warrants to purchase common stock in the offering. The purchase price of each pre-funded warrant will equal the price per share at which shares of common stock are being sold to the public in this offering, minus \$0.01, which constitutes the pre-funded portion of the exercise price, and the remaining unpaid exercise price of the pre-funded warrant will equal \$0.01 per share (subject to adjustment as provided for therein).
-