

PROSPECTUS

**2,000,000 Shares of Common Stock or
Pre-Funded Warrants to Purchase Common Stock
Series A-1 Warrants to Purchase 2,000,000 Shares of Common Stock
Series A-2 Warrants to Purchase 2,000,000 Shares of Common Stock
Placement Agent Warrants to Purchase 140,000 Shares of Common Stock
6,140,000 Shares of Common Stock Underlying the Series A Warrants,
Pre-Funded Warrants and Placement Agent Warrants**

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 up to 2,000,000 shares of our common stock together with Series A-1 warrants to purchase 2,000,000 shares of common stock and Series A-2 warrants to purchase 2,000,000 shares of common stock. The Series A-1 and Series A-2 warrants are collectively referred to herein as the common stock purchase warrants. Each share of our common stock, or a pre-funded warrant in lieu thereof, is being sold together with a Series A-1 warrant to purchase one share of our common stock and a Series A-2 warrant to purchase one share of our common stock. The shares of common stock and common stock purchase warrants are immediately separable and will be issued separately in this offering, but must be purchased together in this offering. The public offering price for each share of common stock and accompanying common stock purchase warrants is \$3.50. Each common stock purchase warrant will have an exercise price per share of \$3.25 and will be immediately exercisable. The common stock purchase warrants will expire on the three-year anniversary of the original issuance date.

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 and accompanying common stock purchase warrants 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 the shares of our common stock to be issued upon exercise of the pre-funded warrants will trade on the Nasdaq Capital Market.

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 June 6, 2023, was \$3.21 per share. The public offering price per share of common stock and accompanying common stock purchase warrants and per pre-funded warrant and accompanying common stock purchase warrants will be determined between us and investors based on market conditions at the time of pricing, and a number of factors, including our history and our prospects, the industry in which we operate, our past and present operating results, the previous experience of our executive officers and the general condition of the securities markets at the time of this offering. There is no established public trading market for the common stock purchase warrants and pre-funded warrants and we do not expect a market for the common stock purchase warrants or the pre-funded warrants to develop. We do not intend to list the common stock purchase warrants or pre-funded warrants on the Nasdaq Capital Market, any other national securities exchange or any other trading system. Without an active trading market, the liquidity of the pre-funded warrants and the common stock purchase warrants will be limited.

We have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering and the placement agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to pay to the placement agent the placement agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. There is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum offering requirement as a condition of closing of this offering. We will bear all costs associated with the offering. See “Plan of Distribution” on page 52 of this prospectus for more information regarding these arrangements.

We are an “emerging growth company” and a “smaller reporting company” as defined under federal securities law 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 18. Neither the U.S. Securities and Exchange Commission (“SEC”) 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 and Common stock purchase warrants	Per Pre-Funded Warrant and Common stock purchase warrants	Total
Public offering price	\$ 3.50	\$ 3.49	\$7,000,000
Placement agent fees ⁽¹⁾	\$0.2450	\$0.2443	\$ 490,000
Proceeds to us, before expenses	\$ 3.255	\$3.2457	\$6,510,000

- (1) We have agreed to pay the placement agent a cash fee equal to 7.0% of the gross proceeds raised in this offering. We have also agreed to reimburse the placement agent for certain of its offering related expenses, including a management fee equal to 1.0% of the aggregate gross proceeds raised in this offering, reimbursement for non-accountable expenses in an amount up to \$50,000, legal fees and other out-of-pocket expenses in the amount of up to \$100,000, and for its clearing expenses in the amount of \$15,950. In addition, we have agreed to issue the placement agent or its designees warrants to purchase a number of shares of common stock equal to 7.0% of the shares of common stock sold in this offering (including the shares of common stock issuable upon the exercise of the pre-funded warrants), at an exercise price of \$4.375 per share, which represents 125% of the public offering price per share and accompanying warrant. For more information about the compensation to be received by the placement agent, see “Plan of Distribution”.

The delivery to purchasers of the shares of common stock, pre-funded warrants, and warrants to purchase common stock in this offering is expected to be made on or about June 9, 2023, subject to satisfaction of certain customary closing conditions.

H.C. Wainwright & Co.

The date of this prospectus is June 6, 2023

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Neither we nor the placement agent have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on our behalf or to which we have referred you. We and the placement agent 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 placement agent are offering to sell, and seeking offers to buy, securities only in jurisdictions where offers and sales are permitted. The information contained in 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 placement agent are offering to sell, and seeking offers to buy, our securities only in jurisdictions where offers and sales are permitted. Neither we nor the placement agent 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 securities 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 Forms 10-K, quarterly reports on Forms 10-Q, current reports on Forms 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;](#)
- [our Definitive Proxy Statement on Schedule 14A \(other than information furnished rather than filed\), filed with the SEC on April 10, 2023;](#)
- [our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 15, 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](#), and [May 22, 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.

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 common stock. 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 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 are conducting studies with TTX-MC138 in support of our planned investigational new drug, or IND, application for a Phase I/II clinical trial with TTX-MC138.

Our other preclinical programs include two solid tumor programs, TTX-siPDL1, an siRNA-based modulator of programmed death-ligand 1, or PD-L1, and TTX-siLIN28B, an siRNA-based inhibitor of RNA-binding protein LIN28B. TransCode also has three cancer-agnostic programs, TTX-RIGA, an RNA-based agonist of the retinoic acid-inducible gene I, or RIG-I, targeting activation of innate immunity in the tumor microenvironment; TTX-CRISPR, a CRISPR/Cas9-based therapy platform for the repair or elimination of cancer-causing genes inside tumor cells; and TTX-mRNA, an mRNA-based platform for the development of cancer vaccines that activate cytotoxic immune responses against tumor cells.

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

Targeted Therapeutic Delivery Background

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

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

TransCode has created a design engine to customize the development of targeted therapeutics that is modular, both at the levels of the core nanoparticle and therapeutic loading. The size, charge, and surface

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

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

Delivery System

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

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

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

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.

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

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

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

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

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

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

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

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

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. Effective therapeutics have not been developed targeting microRNA-10b because, we believe, 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.

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 subjects 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 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 expect to commence enrollment of the Phase 0 trial during the second quarter of 2023. We also anticipate announcing preliminary, topline data from initial patients in this trial early in the second half of 2023. Concurrent with the Phase 0 trial, we expect to continue additional IND-enabling studies to support filing an 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 with a written response due from FDA in approximately 30 days.

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:

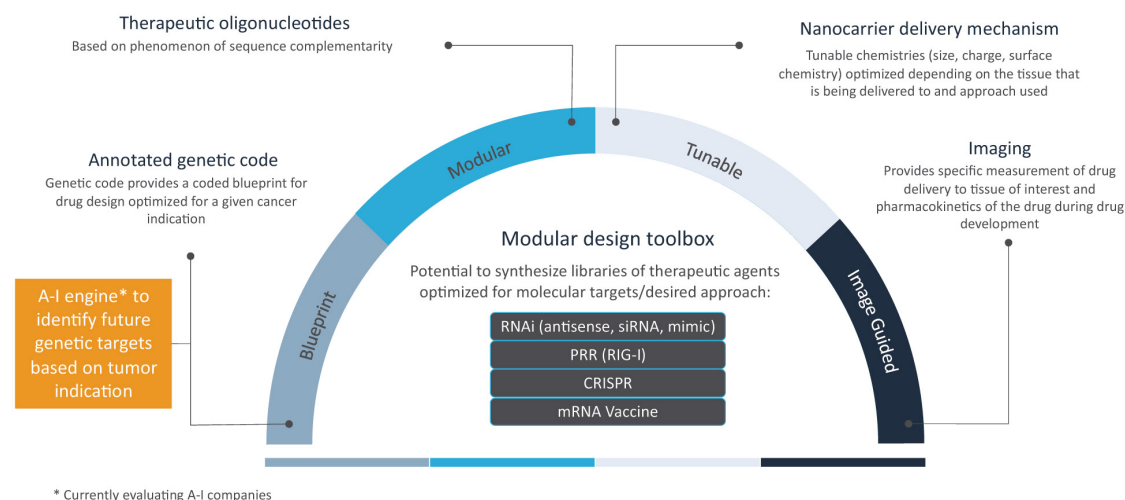
Nanocarrier Delivery Mechanism — Our strategy seeks to leverage a nanoparticle that has been extensively used in humans for imaging by repurposing it to deliver targeted therapeutics to oncology targets and for other therapeutic applications. The nanocarrier is tunable to pre-designed specifications 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 Developments

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.

TTX-MC138 IND-enabling studies

We are conducting IND-enabling studies for TTX-MC138. Upon completion of these studies along with completion of our FDA briefing book, we plan to file an IND with FDA as soon as practical to conduct a Phase 1 clinical trial with TTX-MC138. The scale up and manufacturing of drug product for the IND enabling studies is complete and the remaining nonclinical studies are scheduled to be conducted in the second quarter of 2023.

MDACC Alliance Program

On July 22, 2022, we were chosen as a strategic research alliance partner by MD Anderson Cancer Center, a world-leading cancer research center, to advance preclinical and clinical development of our RNA

therapeutic candidates for oncology applications. Leading the collaboration for MD Anderson are George Calin, MD, PhD, Professor in the Department of Translational Molecular Pathology of Pathology/Lab Medicine, and Co-Director, The RNA Interference and non-coding RNA Center, and a member of our Science Advisory Board, and Vivek Subbiah, MD, Medical Director of the Clinical Center for Targeted Therapy. We believe that being chosen as a strategic research alliance partner by MD Anderson to advance the clinical development of RNA therapeutics is an important step forward for our oncology programs.

Under the five-year strategic collaboration agreement with MD Anderson, we have committed to fund up to \$10 million over the term of the collaboration, with \$500,000 of such amount payable within the first year. Subsequent payments are \$2 million on the first anniversary of the effective date of the agreement and \$2.5 million on each of the second, third and fourth anniversaries thereof. This funding is in line with amounts already budgeted for preclinical and clinical development, so does not represent additional spending. The alliance is expected to provide access to preclinical and clinical resources and expertise for our Phase I/II clinical trials and beyond.

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. 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 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.

Recent Publications

In collaboration with scientists from MGH, Harvard Medical School and Michigan State University, we have published the four 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.

New Patent Applications

TTX-RIGA

TransCode filed U.S. Provisional Patent Application No. 63/356,449 on June 28, 2022. 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 immune system that we anticipate will lead to tumor cell death. This technology potentially enables development of therapeutic candidates to treat advanced cancer patients and may have applicability outside oncology in immune-related indications such as infectious disease. We recently performed our first animal study with TTX-RIGA using a melanoma cell line following *in vitro* proof of concept.

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.

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 begin negotiations of a license to this technology in mid-2023 but there is no assurance that any license will be effected.

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, including in the section entitled “Risk Factors”, and include, but are not limited to, the following:

- 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, commercialization efforts or business activities.
- Our independent public accounting firm has expressed substantial doubt about our ability to continue as a going concern.
- We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.
- We have never generated any revenue from product sales and may never be profitable.
- The amount of our future losses is uncertain, and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- Because our therapeutic candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenues.

- Our business is highly dependent on the success of TTX-MC138, our lead therapeutic candidate which is at the early stages of development. All of 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.
- 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.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of our therapeutic candidates.
- 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.
- We rely on third-parties to conduct certain aspects of our preclinical studies and clinical trials. If these third-parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any therapeutic candidates.
- 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 global pandemic of the novel coronavirus disease, COVID-19, has, and may continue to, adversely impact our business, including our preclinical studies and clinical trials. Dislocations related to the pandemic and the development of vaccines and other treatments for COVID-19 has led to a shortage of animals available for preclinical toxicology and other forms of required testing which could cause delays to our IND-enabling studies or other required testing.

- Our future success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.
- The patents covering our lead therapeutic candidate, TTX-MC138, are currently issued only in the U.S. and there are no foreign applications pending for this invention at this time. We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.
- 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, no exercise of the common stock purchase warrants being offered in this offering, that no value is attributed to such common stock purchase warrants and that such common stock purchase warrants are classified as and accounted for as equity.
- 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.
- We could lose our listing on the Nasdaq Capital Market if the closing bid price of our common stock does not return to above \$1.00 for ten consecutive days during the 180 days ending June 7, 2023, or if we do not regain compliance with Nasdaq Listing Rule 5550(b)(1), which requires companies listed on the Nasdaq Capital Market to maintain stockholders' equity of at least \$2,500,000. The loss of the Nasdaq listing would make our common stock significantly less liquid and would likely adversely affect its value.

Recent Developments

On May 19, 2023, we amended our Certificate of Incorporation to effect a reverse stock split of our outstanding shares of Common Stock by a ratio of 1-for-20. The reverse split was effected on May 23, 2023. Share and per share information included herein has been adjusted to account for the reverse stock split.

Corporate Information

We were incorporated in the State of Delaware in January 2016. The address of our principal executive office 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.

Common Stock and common stock purchase warrants offered by us	THE OFFERING
	<p>2,000,000 shares of our common stock and Series A-1 warrants to purchase up to 2,000,000 shares of common stock and Series A-2 warrants to purchase 2,000,000 shares of common stock, or pre-funded warrants to purchase shares of common stock and common stock purchase warrants to purchase shares of common stock. The shares of common stock or pre-funded warrants, respectively, and common stock purchase warrants are immediately separable and will be issued separately in this offering, but must initially be purchased together in this offering. Each common stock purchase warrant has an exercise price of \$3.25 per share of common stock and is immediately exercisable and will expire three years from the date of the issuance. See “<i>Description of Capital Stock and Securities We Are Offering</i>”. We are also registering 6,140,000 shares of common stock issuable upon exercise of the pre-funded warrants, the common stock purchase warrants, and the placement agent warrants pursuant to this prospectus.</p>
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 and accompanying common stock purchase warrants will equal the price per share of common stock and accompanying common stock purchase warrants 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, subject to ownership limitations. The pre-funded warrants do not expire. To better understand the terms of the pre-funded warrants, you should carefully read the “Description of Capital Stock and Securities We Are Offering” 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⁾	<p>2,901,167 shares of common stock, assuming no sale of any pre-funded warrants, no exercise of the common stock purchase warrants being offered in this offering, that no value is attributed to such common stock purchase warrants and that such common stock purchase warrants are classified as and</p>

	accounted for as equity. To the extent pre-funded warrants are sold, the number of shares of common stock sold in this offering will be reduced on a one-for-one basis.
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; (ii) to fund further research and development of our other therapeutic candidates; and (iii) for working capital and general corporate purposes. See “ <i>Use of Proceeds</i> ” for more information.
Nasdaq Capital Market Symbol	RNAZ
	We do not intend to apply to list the common stock purchase warrants or pre-funded warrants on any national securities exchange or other trading system. Without an active trading market, the liquidity of the common stock purchase warrants and pre-funded warrants will be limited.
Lock-up Agreements	The company and our directors and officers have agreed with the placement agent, 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 60 days after the date of this prospectus. See “ <i>Plan of Distribution</i> ” for more information.
Risk Factors	Investing in our securities involves a high degree of risk. See “ <i>Risk Factors</i> ” beginning on page 18 for important information.
<hr/>	
(1) The number of shares of common stock to be outstanding after the offering is based on 791,167 shares of common stock outstanding as of March 31, 2023, and, as of the date of this prospectus, 110,000 shares of common stock sold to White Lion Capital LLC, or White Lion, since that date under a Common Stock Purchase Agreement dated April 14, 2023, (the “White Lion Purchase Agreement”) by and between us and White Lion and excludes, as of that date, the following:	
<ul style="list-style-type: none"> • 267,276 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of \$10.88 per share; • 31,837 shares of common stock issuable upon the exercise of outstanding common stock purchase warrants at an average exercise price of \$55.16 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:	
<ul style="list-style-type: none"> • no exercise of outstanding options or warrants; • no sale of any pre-funded warrants in lieu of common stock in this offering; and • no exercise of any common stock purchase warrants sold 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 three months ended March 31, 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 Months Ended March 31, 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 three months ended March 31, 2023 and 2022, and balance sheet data as of March 31, 2023, from our unaudited interim financial statements appearing in our [Quarterly Report on Form 10-Q for the Three Months Ended March 31, 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 three months ended March 31, 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.

	Three Months Ended March 31,		Years Ended December 31,	
	2023	2022	2022	2021
	Unaudited			
Statement of Operations Data				
Operating expenses				
Research and development	\$ 2,591,350	\$ 1,881,576	\$ 10,232,366	\$ 2,753,966
General and administrative	2,309,763	1,595,926	8,433,448	3,397,169
Total operating expenses	4,901,113	3,477,502	18,665,814	6,151,135
Operating loss	(4,901,113)	(3,477,502)	(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	79,409	6,990	1,080,436	278,333
Loss on sale of equipment	—	—	—	(3,082)
Interest expense	—	—	—	(95,070)
Interest income	4,770	442	20,410	664
Total other income (expense)	84,179	7,432	1,100,846	(692,264)
Loss before income taxes	(4,816,934)	(3,470,070)	(17,564,968)	(6,843,399)
Income tax expense (benefit)	—	—	—	—
Net loss	<u><u>\$(4,816,934)</u></u>	<u><u>\$(3,470,070)</u></u>	<u><u>\$(17,564,968)</u></u>	<u><u>\$(6,843,399)</u></u>
Basic and diluted loss per common share ⁽¹⁾	<u><u>\$ (6.69)</u></u>	<u><u>\$ (5.35)</u></u>	<u><u>\$ (27.07)</u></u>	<u><u>\$ (16.24)</u></u>
Weighted average number of common shares outstanding, basic and diluted ⁽¹⁾	720,019	648,861	648,861	421,294

	March 31, 2023	December 31,	
	Unaudited	2022	2021
Balance Sheet Data			
Current assets	\$4,346,623	\$7,379,405	\$22,732,175
Total assets	5,590,510	7,587,986	22,938,443
Current liabilities	5,449,489	4,347,290	2,534,097
Total liabilities	5,827,302	4,347,290	2,534,097
Total stockholders' equity (deficit)	(236,792)	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](#), 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

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

As of March 31, 2023, we had cash totaling approximately \$1.6 million. We do not believe that our cash as of March 31, 2023, will enable us to fund our operating expenses and capital requirements through the second quarter of 2023. We will need to raise additional capital to continue as a going concern. Our recurring losses from operations and negative cash flow raise substantial doubt about our ability to continue as a going concern without sufficient capital resources. Our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the years ended December 31, 2022, and 2021, with respect to this uncertainty. Our ability to continue as a going concern is dependent on both our available cash and how well we manage that cash and our operating requirements. We believe that the net proceeds from this offering, together with our existing cash and funds we received under our SBIR award in April 2023, will be sufficient to fund our current operating plans into the second-half of 2023. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect and need to raise additional funds sooner than we anticipate. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our research and development programs and commercialization efforts.

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 through the second quarter of 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 and funds we received under our SBIR award in April 2023, will be sufficient to fund our operations into the second-half 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;
- 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

This is a best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth herein. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations, including our near-term continued operations. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds to complete such short-term operations. Such additional fundraises may not be available or available on terms acceptable to us.

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

Prior to our initial public offering, there had been no public market for shares of our common stock and since then the 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. 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 and has declined significantly from our initial public offering price. 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.

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 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 public offering price of \$3.50 per share and accompanying common stock purchase warrants, purchasers of securities in this offering will experience immediate dilution of \$1.30 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 common stock purchase warrants or pre-funded warrants sold in this offering.

There is no established public trading market for the common stock purchase warrants or pre-funded warrants being sold in this offering. We will not list the common stock purchase warrants or 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 common stock purchase warrants or pre-funded warrants. Without an active market, the liquidity of the common stock purchase warrants and pre-funded warrants will be limited.

The common stock purchase warrants and pre-funded warrants are speculative in nature.

The common stock purchase warrants and 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 common stock purchase warrants and 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 common stock purchase warrants or pre-funded warrants acquire shares of our common stock upon exercise thereof, holders of such common stock purchase warrants or pre-funded warrants will have no rights with respect to shares of our common stock. Upon exercise of the common stock purchase warrants or 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.

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 approximately 23.7% of our outstanding common stock as of May 31, 2023, or approximately 21.3% of our outstanding common stock after giving effect to the sale of 2,000,000 shares of common stock and accompanying common stock purchase warrants in this offering at the combined public offering price of \$3.50 per share and accompanying common stock purchase warrants. The foregoing calculations exclude shares issuable pursuant to the accompanying common stock purchase warrants being sold in this offering and the possible exercise of options. If the specified individuals exercised all options they hold, and no other options were exercised by any other holder and excluding shares issuable pursuant to the accompanying common stock purchase warrant being sold in this offering, the holdings of the specified individuals would represent beneficial ownership, in the aggregate, of approximately 35.5% of our outstanding common stock prior to this offering, or approximately 32.5% of our outstanding common stock after giving effect to the sale of 2,000,000 shares of common stock in this offering but excluding shares issuable pursuant to the accompanying common stock purchase warrants being sold in this offering. As a result of their combined ownership, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation or sale of all or substantially all of our assets. These stockholders acquired 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 in our initial public offering or 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
- 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. 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 the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal controls over financial reporting. Furthermore, we may not have identified all material weaknesses, and our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Accordingly, there continues to be a reasonable possibility that these deficiencies or others could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis.

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

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

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an EGC, our independent registered public accounting firm will not be required to attest

to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or by-laws or (v) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternate forum, the United 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.

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

We could lose our listing on the Nasdaq Capital Market if the closing bid price of our common stock does not return to above \$1.00 for ten consecutive days during the 180 days ending June 7, 2023, or if we do not increase our stockholders' equity. The loss of the Nasdaq listing would make our common stock significantly less liquid and would adversely affect its value.

As initially disclosed on the Current Report on Form 8-K filed on December 9, 2022, with the SEC, we received written notification from Nasdaq notifying us that our stock had failed to comply with Nasdaq Listing Rule 5550(a)(2), or the Minimum Bid Price Requirement, because the bid price for our common stock for 30 consecutive business days prior to such date had closed below the minimum \$1.00 per share

requirement for continued listing. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), or the Compliance Period Rule, we have been provided an initial period of 180 calendar days, or until June 7, 2023, or the Compliance Date, to regain compliance with the Minimum Bid Price Requirement. If, at any time during this 180-day period, the closing bid price for our common stock closes at \$1.00 or more per share for a minimum of 10 consecutive business days, as required under the Compliance Period Rule, Nasdaq will provide written notification to us that our stock complies with the Minimum Bid Price Requirement and the common stock will continue to be eligible for listing on the Nasdaq Capital Market.

If we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would be required meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional compliance period.

If it appears to the Nasdaq staff that we will not be able to cure the deficiency, the Nasdaq staff will provide written notice to us that our common stock will be subject to delisting. At that time, we may appeal the staff's delisting determination to a Nasdaq Hearing Panel, or the Panel. We expect that our stock would remain listed pending the Panel's decision. There can be no assurance that, if we do appeal any such delisting determination to the Panel, such appeal would be successful.

On May 19, 2023, we amended our Certificate of Incorporation to effect a reverse stock split of our outstanding shares of Common Stock by a ratio of 1-for-20. The reverse split became effective May 23, 2023. There is no assurance that even after the reverse split, our common stock will remain above the Minimum Bid Price Requirement.

In addition, as disclosed on our Current Report on Form 8-K filed with the SEC on May 18, 2023, we received a notice from Nasdaq on May 16, 2023, that our stockholders' equity at March 31, 2023, does not meet the amount required for continued listing. We have 45 calendar days to submit a plan to Nasdaq describing how we intend to seek to regain compliance. If our plan is accepted, Nasdaq may grant an extension of up to 180 calendar days from the date of the notice to evidence compliance. There is no assurance that our plan will be accepted by Nasdaq or, if it is, that we will be successful in achieving the required stockholders' equity.

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.

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 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 described above and otherwise, including but not limited to our ability to enroll a sufficient number of patients to advance the above-described clinical trial;
- the results and timing of our preclinical and clinical trial activities;
- the therapeutic benefits, effectiveness and safety of our therapeutic candidates;
- our ability to receive regulatory approval for our therapeutic candidates in the United States, Europe and other geographies;
- the expected regulatory approval pathway for our therapeutic candidates, and our ability to obtain, on satisfactory terms or at all, the financing required to support operations, research, development, clinical trials, and commercialization of products;
- our reliance on third-parties for the planning, conduct and monitoring of clinical trials, for the manufacture of clinical drug supplies and drug product, and for other requirements;
- potential changes in regulatory requirements, and delays or negative outcomes from the regulatory approval process;
- our estimates of the size and characteristics of the markets that may be addressed by our therapeutic candidates;
- market acceptance of our therapeutic candidates that are approved for marketing in the United States or other countries;
- our ability to successfully commercialize our therapeutic candidates;
- the safety and efficacy of therapeutics marketed by our competitors that are targeted to indications which our therapeutic candidates have been developed to treat;
- the impact of natural disasters, global pandemics (including further outbreaks of existing strains of COVID-19 or new variants of the virus), labor disputes, lack of raw materials or other supplies, issues with facilities and equipment or other forms of disruption to business operations at our manufacturing or laboratory facilities or those of our vendors;
- our ability to utilize our proprietary technological approach to develop and commercialize our therapeutic candidates;
- potential collaborators to license and commercialize any therapeutic candidates for which we receive regulatory approval in the future in or outside of the United States;

- our heavy dependence on licensed intellectual property, including our ability to source and maintain licenses from third-party owners;
- our ability to protect our intellectual property and operate our business without infringing the intellectual property rights of others;
- our ability to attract, retain and motivate key personnel;
- our ability to generate revenue and become profitable;
- a potential delisting of our common stock from trading on the Nasdaq Capital Market if the closing bid price of our common stock does not return to above \$1.00 for ten consecutive days during the 180 days ending June 7, 2023, or if our plan to regain compliance with the minimum stockholders' equity requirement is not accepted and any appeal of the non-acceptance we might make is not approved; and
- other risks and uncertainties, including those listed under the caption "*Risk Factors*" of this prospectus.

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, including estimates regarding the impact of the COVID-19 pandemic (or related pandemics caused by coronavirus variants) on our business, prospects, results of operations, and financial condition. 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 placement agent fees and other offering expenses payable by us and assuming no sale of any pre-funded warrants, no exercise of the common stock purchase warrants being offered in this offering, that no value is attributed to such common stock purchase warrants and that such common stock purchase warrants are classified as and accounted for as equity, will be approximately \$6.1 million, based on the public offering price of \$3.50 per share and accompanying common stock purchase warrants.

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, for further research and development of our other therapeutic candidates, 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.

We believe that the net proceeds from this offering, together with our existing cash, including funds we received under our SBIR award in April 2023, and from sales of our common stock to White Lion, will enable us to fund our operating expenses and capital expenditure requirements into the second-half 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 also believe that the amount of net proceeds from this offering allocated to preclinical development work on certain of our other therapeutic candidates will be sufficient to complete limited preclinical development. Thus, 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.

DILUTION

If you invest in our securities 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 and accompanying warrant and the as adjusted net tangible book value per share of our common stock immediately after this offering (in each case, assuming no pre-funded warrants are sold in this offering, no exercise of the common stock purchase warrants being offered in this offering, that no value is attributed to such common stock purchase warrants and that such common stock purchase warrants are classified as and accounted for as equity).

As adjusted to give effect to our sale of 110,000 shares of our common stock for net proceeds of \$518,844 under the White Lion Purchase Agreement through the date of this prospectus, at March 31, 2023, we had a pro forma net tangible book value of \$282,052 or \$0.313 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 at that date.

After giving effect to the sale and issuance of 2,000,000 shares of common stock and accompanying common stock purchase warrants in this offering, at the public offering price of \$3.50 per share and accompanying common stock purchase warrants, after deducting placement agent fees and other offering expenses payable by us, our as adjusted pro forma net tangible book value at March 31, 2023, would have been \$6,372,052, or \$2.20 per share of our common stock (assuming no pre-funded warrants are sold in this offering, no exercise of the common stock purchase warrants being offered in this offering, that no value is attributed to such common stock purchase warrants and that such common stock purchase warrants are classified as and accounted for as equity). This represents an immediate increase in pro forma net tangible book value of approximately \$1.89 per share to our existing stockholders and an immediate dilution of \$1.30 per share to new investors.

The dilutive effect per share to investors participating in this offering is determined by subtracting the as adjusted pro forma net tangible book value per share after this offering from the public offering price per share and accompanying common stock purchase warrants paid by investors participating in this offering. The following table illustrates this result on a per share basis:

Public offering price per share and accompanying common stock purchase warrant	<u>\$3.50</u>
Pro forma net tangible book value per share at March 31, 2023	<u>\$0.31</u>
Increase in book value per share attributable to new investors	<u>\$1.89</u>
As adjusted pro forma net tangible book value per share after this offering	<u>\$2.20</u>
Dilution per share to new investors	<u><u>\$1.30</u></u>

The table and discussion above are based on 791,167 shares of common stock outstanding at March 31, 2023, and 110,000 shares of common stock subsequently sold to White Lion under the White Lion Purchase Agreement as of the date of this prospectus, assume no sale of any pre-funded warrants, and exclude, as of that date, the following:

- 267,276 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of \$10.88 per share;
- 31,837 shares of common stock issuable upon the exercise of outstanding common stock purchase warrants at an average exercise price of \$55.16 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 in connection with 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, 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 March 31, 2023, 791,167 shares of common stock were outstanding held by approximately 20 stockholders of record and, subsequent to that date, an additional 110,000 shares of common stock were sold to White Lion under the White Lion Purchase Agreement as of the date of this prospectus. As of the date of this prospectus, 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 the date of this prospectus, 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) 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 IPO, our

Board of Directors determined that no further awards under the 2020 Plan would be made. At that time, there were 89,633 shares subject to options outstanding under the 2020 Plan.

As of May 31, 2023, options to purchase an aggregate of 267,276 shares of our common stock were outstanding under the Plans, of which 89,228 were exercisable.

Prior Warrants

Upon the closing of our IPO, we issued as compensation to the underwriter warrants, or the underwriter's warrants, to purchase up to 15,625 shares of common stock exercisable at \$100.00 per share. The underwriter's 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 placement agent's warrants, to purchase up to 9,962 shares of common stock exercisable at \$13.18 per share. The placement agent's 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 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. On May 31, 2023, we exercised this right.

Common Stock Purchase Warrants

The following summary of certain terms and provisions of the common stock purchase warrants offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the common stock purchase 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 common stock purchase warrant for a complete description of the terms and conditions of the common stock purchase warrants.

Duration and Exercise Price. Each common stock purchase warrant offered hereby will have an exercise price of \$3.25 per share. The common stock purchase warrants will be immediately exercisable and may be exercised until three years from the date of issuance. The exercise price and number of shares of common stock issuable upon exercise of the common stock purchase warrants 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. The common stock purchase warrants will be issued separately from the common stock or pre-funded warrants, respectively, and may be transferred separately immediately thereafter. The common stock purchase warrants will be issued in certificated form only.

Exercisability. The common stock purchase 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 such holder's common stock purchase warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's common stock purchase warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common stock purchase warrants. The ownership limit may be decreased upon notice from the holder to us.

Cashless Exercise. If, at the time a holder exercises its warrants, a registration statement registering the issuance or resale of the shares of common stock underlying the common stock purchase warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate

exercise price, 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 common stock purchase warrant.

Fundamental Transactions. In the event of a fundamental transaction, as described in the common stock purchase warrants and generally including any reorganization, recapitalization or reclassification of our shares of 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 50% or more of the voting power represented by our outstanding shares of capital stock, any person or group becoming the beneficial owner of 50% or more of the voting power represented by our outstanding shares of capital stock, any merger with or into another entity or a tender offer or exchange offer approved by 50% or more of the voting power represented by our outstanding shares of capital, then upon any subsequent exercise of a warrant, the holder will have the right to receive as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of our common stock for which the common stock purchase warrant is exercisable immediately prior to such event. Notwithstanding the foregoing, in the event of a fundamental transaction, the holders of the common stock purchase warrants have the right to require us or a successor entity to redeem the common stock purchase warrants for cash in the amount of the Black-Scholes Value (as defined in each common stock purchase warrant) of the unexercised portion of the common stock purchase warrants concurrently with or within 30 days following the consummation of a fundamental transaction.

However, in the event of a fundamental transaction which is not in our control, including a fundamental transaction not approved by our board of directors, the holders of the common stock purchase warrants will only be entitled to receive from us or our successor entity, as of the date of consummation of such fundamental transaction the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the common stock purchase warrants that is being offered and paid to the holders of our common stock in connection with the fundamental transaction, whether that consideration is in the form of cash, stock or any combination of cash and stock, or whether the holders of our common stock are given the choice to receive alternative forms of consideration in connection with the fundamental transaction. If holders of our common stock are not offered or paid any consideration in the fundamental transaction, holders of common stock will be deemed to have received common stock of our successor entity.

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

Fractional Shares. No fractional shares of common stock will be issued upon the exercise of the common stock purchase warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the next whole share or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Trading Market. There is no established trading market for the common stock purchase warrants, and we do not expect such a market to develop. We do not intend to apply to list the common stock purchase warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the common stock purchase warrants will be extremely limited.

No Rights as a Stockholder. Except as otherwise provided in the common stock purchase warrants or by virtue of the holder's ownership of shares of our common stock, such holder of common stock purchase warrants does not have the rights or privileges of a holder of our common stock, including any voting rights, until such holder exercises such holder's common stock purchase warrants.

Waivers and Amendments. The common stock purchase warrants may be modified or amended or the provisions of such common stock purchase warrants waived with our consent and the consent of the holders of at least a majority of the outstanding warrants.

Pre-Funded Warrants

The following summary of certain terms and provisions of the pre-funded warrants offered hereby in lieu of shares of common stock 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. The common stock purchase warrants will provide that the holders of the pre-funded warrants have the right to participate in distributions or dividends paid on our shares of common stock.

Placement Agent Warrants

The following summary of certain terms and provisions of the placement agent warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of warrants, the forms of which are 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 forms of warrant for a complete description of the terms and conditions of the warrants.

Duration and Exercise Price. Each Placement Agent Warrant offered hereby will have an initial exercise price equal to \$4.375 per share of common stock (125% of the public offering price per share of common stock). The Placement Agent Warrants will be immediately exercisable and will expire three years from the closing of the offering. 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 Placement Agent Warrants may be exercised, in cash or by a cashless exercise at the election of the holder at any time 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. Each Placement Agent Warrant may be exercised, in cash or by a cashless exercise at the election of the holder at any time following the date of issuance and from time to time thereafter through and including three years of the initial exercise date. The Placement Agent 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 such holder's Placement Agent Warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Placement Agent Warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Placement Agent Warrants. The ownership limit may be decreased upon notice from the holder to us.

Cashless Exercise. If, at the time a holder exercises its Placement Agent Warrants, a registration statement registering the issuance or resale of the shares of common stock underlying the Placement Agent Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, 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 Placement Agent Warrants.

Fundamental Transactions. In the event of a fundamental transaction, as described in the Placement Agent Warrants and generally including any reorganization, recapitalization or reclassification of our shares of 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 50% or more of the voting power represented by our outstanding shares of capital stock, any person or group becoming the beneficial owner of 50% or more of the voting power represented by our outstanding shares of capital stock, any merger with or into another entity or a tender offer or exchange offer approved by 50% or more of the voting power represented by our outstanding shares of capital, then upon any subsequent exercise of a Placement Agent Warrant, the holder will have the right to receive as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of our common stock for which the Placement Agent Warrant is exercisable immediately prior to such event. Notwithstanding the foregoing, in the event of a fundamental transaction, the holders of the Placement Agent Warrants have the right to require us or a successor entity to redeem the Placement Agent Warrants for cash in the amount of the Black-Scholes Value (as defined in each Placement Agent Warrant) of the unexercised portion of the Placement Agent Warrants concurrently with or within 30 days following the consummation of a fundamental transaction.

However, in the event of a fundamental transaction which is not in our control, including a fundamental transaction not approved by our board of directors, the holders of the Placement Agent Warrants will only be entitled to receive from us or our successor entity, as of the date of consummation of such fundamental transaction the same type or form of consideration (and in the same proportion), at the Black Scholes Value

of the unexercised portion of the Placement Agent Warrant that is being offered and paid to the holders of our common stock in connection with the fundamental transaction, whether that consideration is in the form of cash, stock or any combination of cash and stock, or whether the holders of our common stock are given the choice to receive alternative forms of consideration in connection with the fundamental transaction. If holders of our common stock are not offered or paid any consideration in the fundamental transaction, holders of common stock will be deemed to have received common stock of our successor entity.

Transferability. Subject to applicable laws, a Placement Agent Warrant may be transferred at the option of the holder upon surrender of the Placement Agent Warrant to us together with the appropriate instruments of transfer.

Fractional Shares. No fractional shares of common stock will be issued upon the exercise of the Placement Agent Warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the next whole share or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Trading Market. There is no established trading market for the Placement Agent Warrants, and we do not expect such a market to develop. We do not intend to apply to list the Placement Agent Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Placement Agent Warrants will be extremely limited.

No Rights as a Stockholder. Except as otherwise provided in the Placement Agent Warrants or by virtue of the holder's ownership of shares of our common stock, such holder of Placement Agent Warrants does not have the rights or privileges of a holder of our common stock, including any voting rights, until such holder exercises such holder's Placement Agent Warrants.

Waivers and Amendments. The warrants may be modified or amended or the provisions of such warrants waived with our consent and the consent of the holders of a majority of the outstanding warrants.

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, 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;
- 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 [26](#) under the caption "We could lose our listing on the Nasdaq Capital Market if

the closing bid price of our common stock does not return to above \$1.00 for ten consecutive days during the 180 days ending June 7, 2023, or if we do not increase our stockholders' equity. The loss of the Nasdaq listing would make our common stock significantly less liquid and would adversely affect its value."

Transfer Agent and Registrar

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

We will act as transfer agent for warrants.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS TO NON-U.S. HOLDERS

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, (ii) the purchase, ownership, disposition and lapse of the common stock purchase warrants and (iii) the purchase, ownership and disposition of the pre-funded warrants. The Shares, common stock purchase warrants 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(l)(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.

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 \$0.01 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.

Allocation of Purchase Price

Each purchaser of Shares or pre-funded warrants must allocate its purchase price for such shares or pre-funded warrants between each Share or pre-funded warrant, as applicable and the accompanying common stock purchase warrant based on the respective relative fair market values of each at the time of issuance. This allocation of the purchase price will establish the holder's initial tax basis for U.S. federal income tax purposes for each Share, pre-funded warrant and common stock purchase warrant. A holder's allocation of the purchase price among the Shares, pre-funded warrants and common stock purchase warrants is not binding on the IRS or the courts, and no assurance can be given that the IRS or the courts will agree with a holder's allocation. Each holder should consult its tax advisor regarding the allocation of the purchase price among the Shares, pre-funded warrants and common stock purchase warrants.

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 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 Common Stock Purchase Warrants and 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 common stock purchase warrants or the pre-funded warrants, or an adjustment to (or failure to adjust) the exercise price of the common stock purchase warrants or the pre-funded warrants, may be treated as a constructive distribution to a U.S. holder of the common stock purchase warrants or the pre-funded warrants, as applicable, 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 common stock purchase warrants, 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 a common stock purchase warrant or 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, common stock purchase warrants (other than by exercise) 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.

Exercise, Lapse, or Redemption of a Common Stock Purchase Warrant

Except as discussed below with respect to the cashless exercise of a common stock purchase warrant, a U.S. holder generally will not recognize gain or loss upon the exercise of a common stock purchase warrant. A U.S. holder’s tax basis in a Share received upon exercise of the common stock purchase warrant generally will be an amount equal to the sum of the U.S. holder’s initial investment in the common stock purchase warrant and the exercise price. The U.S. holder’s holding period for the Share received upon exercise of the common stock purchase warrant generally will commence on the date of exercise of the common stock

purchase warrant or the date following the date of exercise of the common stock purchase warrant; however, in either case the holding period will not include the period during which the U.S. holder held the common stock purchase warrant. If a common stock purchase warrant is allowed to lapse unexercised, a U.S. holder generally will recognize a capital loss equal to such holder's tax basis in the common stock purchase warrant.

The tax consequences of a cashless exercise of a common stock purchase warrant are not clear under current tax law. A cashless exercise may be tax-free, either because the exercise is not a gain realization event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In either tax-free situation, a U.S. holder's basis in the Shares received would equal the holder's basis in the common stock purchase warrants used to effect the cashless exercise. If the cashless exercise is not treated as a gain realization event, a U.S. holder's holding period in the Shares generally would be treated as commencing on the date of exercise of the common stock purchase warrant or the date following the date of exercise of the common stock purchase warrant; however, in either case the holding period will not include the period during which the U.S. holder held the common stock purchase warrant. If the cashless exercise were treated as a recapitalization, the holding period of the Shares would include the holding period of the common stock purchase warrant.

It is also possible that a cashless exercise could be treated in part as a taxable exchange in which gain or loss would be recognized. In such event, a portion of the common stock purchase warrants to be exercised on a cashless basis could, for U.S. federal income tax purposes, be deemed to have been surrendered in consideration for the exercise price of the remaining common stock purchase warrants, which would be deemed to be exercised. For this purpose, a U.S. holder could be deemed to have surrendered common stock purchase warrants having an aggregate fair market value equal to the exercise price for the total number of common stock purchase warrants to be deemed exercised. The U.S. holder would recognize capital gain or loss in an amount equal to the difference between the fair market value of the common stock purchase warrants deemed surrendered and the U.S. holder's tax basis in such common stock purchase warrants. In this case, a U.S. holder's tax basis in the Shares received would equal the sum of the U.S. holder's initial investment in the common stock purchase warrants deemed exercised and the exercise price of such common stock purchase warrants. A U.S. holder's holding period for the Shares in such case generally would commence on the date following the date of exercise (or possibly the date of exercise) of the common stock purchase warrant.

Due to the absence of authority on the U.S. federal income tax treatment of a cashless exercise, there can be no assurance which, if any, of the alternative tax consequences and holding periods described above would be adopted by the IRS or a court of law. Accordingly, U.S. holders should consult their tax advisors regarding the tax consequences of a cashless exercise.

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.

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 common stock purchase warrants or the pre-funded warrants, as described above under “Tax Considerations Applicable to U.S. Holders — Constructive Dividends on Common Stock Purchase Warrants and 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, common stock purchase warrants or pre-funded warrants, as applicable, 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, common stock purchase warrants 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.

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 common stock purchase warrants and 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 common stock purchase warrants or 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 common stock purchase warrants and our pre-funded warrants are not expected to be regularly traded on an established securities market. Dispositions by a non-U.S. holder of common stock purchase warrants or 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 common stock purchase warrants or pre-funded warrants were acquired, as applicable, 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 common stock purchase warrants or 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.

Exercise, Lapse, or Redemption of a Common Stock Purchase Warrant

A non-U.S. holder generally will not recognize gain or loss for U.S. federal income tax purposes on the exercise of a warrant and the related receipt of Shares underlying the common stock purchase warrant.

See “— Tax Considerations Applicable to U.S. Holders — Exercise, Lapse, or Redemption of a Common Stock Purchase Warrant.” However, if a cashless exercise of common stock purchase warrants results in a taxable exchange, as described in “— Tax Considerations Applicable to U.S. Holders — Exercise, Lapse, or Redemption of a Common Stock Purchase Warrant,” the rules described above under “— Sale or Other Taxable Disposition of Our Securities” would apply. If a non-U.S. holder allows a common stock purchase warrant to expire unexercised, such non-U.S. holder will recognize a capital loss for U.S. federal income tax purposes in an amount equal to such holder’s tax basis in the common stock purchase warrant. See “— Tax Considerations Applicable to U.S. Holders — Tax Considerations Applicable to U.S. Holders — Exercise, Lapse, or Redemption of a Common Stock Purchase Warrant” above.

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 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, common stock purchase warrants 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.

PLAN OF DISTRIBUTION

We have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent to solicit offers to purchase the shares of our common stock, pre-funded warrants and common stock purchase warrants offered by this prospectus. The placement agent is not purchasing or selling any such securities, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of such securities, other than to use its “reasonable best efforts” to arrange for the sale of such securities by us. Therefore, we may not sell all of the shares of common stock, pre-funded warrants and common stock purchase warrants being offered. The terms of this offering were subject to market conditions and negotiations between us, the placement agent and prospective investors. The placement agent will have no authority to bind us by virtue of the engagement letter. This is a best efforts offering and there is no minimum offering amount required as a condition to the closing of this offering. The placement agent may retain sub-agents and selected dealers in connection with this offering. Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract is material to larger purchasers in this offering as a means to enforce the following covenants uniquely available to them under the securities purchase agreement: (i) a covenant to not enter into variable rate financings for a period of one year following the closing of the offering, subject to an exception; and (ii) a covenant to not enter into any equity financings for 60 days from closing of the offering, subject to certain exceptions.

The nature of the representations, warranties and covenants in the securities purchase agreements shall include:

- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act; and
- covenants regarding matters such as registration of warrant shares, no integration with other offerings, filing of an 8-K to disclose entering into these securities purchase agreements, no shareholder rights plans, no material nonpublic information, use of proceeds, indemnification of purchasers, reservation and listing of common stock, and no subsequent equity sales for 60 days.

Delivery of the shares of common stock, pre-funded warrants and common stock purchase warrants offered hereby is expected to occur on or about June 9, 2023, subject to satisfaction of certain customary closing conditions.

We have agreed to pay the placement agent an aggregate fee equal to 7.0% of the gross proceeds received in the offering and a management fee equal to 1.0% of the gross proceeds raised in the offering. In addition, we have agreed to reimburse the placement agent for non-accountable fees and expenses of \$50,000, its legal fees and expenses and other out-of-pocket expenses in an amount up to \$100,000 and clearing expenses of \$15,950.

We have agreed to issue to the placement agent and its designees warrants to purchase that number of shares of our common stock equal to 7.0% of the aggregate number of shares of common stock (or common stock equivalents) issued in this offering. The exercise price per share of common stock of those warrants is \$4.375 (125% of the combined public offering price per share of common stock and Series A warrants) and will terminate on the three-year anniversary of the closing of the offering. The Placement Agent Warrants are registered on the registration statement of which this prospectus is a part. The form of the Placement Agent Warrants is included as an exhibit to this registration statement of which this prospectus forms a part.

We have previously granted the placement agent a right of first refusal until February 17, 2024, to act as exclusive financial advisor, sole book-running manager, sole underwriter, sole placement agent or sole agent for each and every future debt financing or refinancing and public or private equity offering or acquisition or disposition by us or any of our successors or subsidiaries when we seek an investment banker or financial advisor.

We estimate the total expenses of this offering paid or payable by us, exclusive of the placement agent's cash fee of 7% of the gross proceeds and expenses, will be approximately \$425,000. After deducting the fees due to the placement agent and our estimated expenses in connection with this offering, we expect the net proceeds from this offering will be approximately \$6.1 million (based on the public offering price per share and accompanying common stock purchase warrants of 3.50).

The following table shows the per share and total cash fees we will pay to the placement agent in connection with the sale of the common stock and shares of common stock underlying the common stock purchase warrants and pre-funded warrants pursuant to this prospectus.

	Per Share and Common stock purchase warrants	Per Pre-Funded Warrant and Common stock purchase warrants	Total
Offering Price	\$ 3.50	\$ 3.49	\$7,000,000
Placement agent fees	0.245	0.2443	\$ 490,000
Proceeds to us, before expenses	\$3.255	\$3.2457	\$6,510,000

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in our engagement letter with the placement agent. We have also agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

Lock-up Agreements

We and each of our officers and directors have agreed with the placement agent to be subject to a lock-up period of 60 days following the date of closing of the offering pursuant to this prospectus. This means that, during the applicable lock-up period, we and such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any of our shares of common stock or any securities convertible into, or exercisable or exchangeable for, shares of common stock, subject to customary exceptions. The placement agent may waive the terms of these lock-up agreements in its sole discretion and without notice. In addition, for a period of one year following the closing date of this offering, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our common stock or upon a specified or contingent event in the future or enter into any agreement to issue securities at a future determined price, subject to an exception. The placement agent may waive this prohibition in its sole discretion and without notice.

Tail

We have also agreed to pay the placement agent a tail fee equal to the cash and warrant compensation in this offering, if any investor, who was contacted or introduced to us by the placement agent during the term of its engagement who was not a prior investor in us, provides us with capital in any public or private offering or other financing or capital raising transaction during the 12-month period following expiration or termination of our engagement of the placement agent.

Other Relationships

From time to time, the placement agent may provide in the future various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. However, except as disclosed in this prospectus, we have no present arrangements with the placement agent for any further services. The placement agent acted as the placement agent in connection with our previous offering consummated in February 2023, for which it received customary fees and expenses.

Regulation M Compliance

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the sale of our securities offered hereby by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent will be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Listing and Transfer Agent

Our common stock is listed on Nasdaq and trades under the symbol “RNAZ.” The transfer agent of our common stock is VStock Transfer, LLC. There is no established public trading market for the common stock purchase warrants or pre-funded warrants, and we do not plan on making an application to list the common stock purchase warrants or pre-funded warrants on Nasdaq, any national securities exchange or other nationally recognized trading system. We will act as the registrar and transfer agent for the warrants.

Electronic Distribution

This prospectus in electronic format may be made available on websites or through other online services maintained by the placement agent, or by its affiliates. Other than this prospectus in electronic format, the information on the placement agent’s website and any information contained in any other website maintained by the placement agent is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent in its capacity as an underwriter, and should not be relied upon by investors.

LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Goodwin Procter 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.

**2,000,000 Shares of Common Stock or
Pre-Funded Warrants to Purchase Shares of Common Stock
Series A-1 Warrants to Purchase 2,000,000 Shares of Common Stock
Series A-2 Warrants to Purchase 2,000,000 Shares of Common Stock
Placement Agent Warrants to Purchase up to 140,000 Shares of Common Stock
6,140,000 Shares of Common Stock Underlying the Series A Warrants,
Pre-Funded Warrants and Placement Agent Warrants**

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.

PROSPECTUS

H.C. Wainwright & Co.

June 6, 2023
