TransCode Therapeutics, Inc.

2026 Annual Report

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number: 001-40363

TRANSCODE THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, $0.0001 par value per share	RNAZ	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the Registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the Registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 30, 2025, the last day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the Registrant's common stock held by non-affiliates of the Registrant was approximately $6.5 million, based upon the closing price of the Registrant's common stock on June 30, 2025. In determining the market value of non-affiliate common stock, shares of the Registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of April 3, 2026, was 916,968.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates by reference certain information from the Registrant's definitive Proxy Statement for its 2026 annual meeting of stockholders, which the Registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the Registrant's fiscal year end of December 31, 2025. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

TRANSCODE THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws, Section 27A of the Securities Act of 1933, as amended, (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are included in this statement for purposes of complying with those safe harbor provisions. All statements other than statements of historical facts contained in this Annual Report on Form 10-K 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 ability to obtain stockholder approvals allowing for (i) the issuance of common stock upon the conversion of our Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share, and Series B Non-Voting Convertible Preferred Stock, par value $0.0001 per share, in connection with our acquisition of ABCJ, LLC, the parent company of Polynoma, LLC ("Polynoma") pursuant to a Membership Interest Purchase Agreement, dated October 8, 2025, (ii) the issuance of common stock upon the conversion of our Series C Non-Voting Convertible Preferred Stock, par value $0.0001 per share issued pursuant to our licensing agreement with Unleash Immuno Oncolytics, Inc. ("Unleash"), dated March 2, 2026, and the respective timing thereof, and (iii) the potential issuance of shares of common stock pursuant to a Standby Equity Purchase Agreement (the "SEPA") by and between us and YA II PN, LTD ("Yorkville");
- our cash position, our estimates and expectations regarding our capital requirements, cash and expense levels, liquidity sources, our need for additional financing and our ability to obtain, on satisfactory terms or at all, the financing required to support operations, research, development, clinical trials, and commercialization of products;
- a potential delisting of our common stock from trading on the Nasdaq Capital Market;
- our ability to continue as a going concern;
- the results and timing of our preclinical and clinical trial activities, including but not limited to our ability to enroll a sufficient number of patients timely to advance our clinical trials;
- our ability to expand our therapeutic candidate portfolio through internal research and development or the acquisition or in-licensing of intellectual property assets;
- the therapeutic benefits, effectiveness and safety of our therapeutic candidates;
- our ability to receive regulatory approval for our therapeutic candidates in the United States, Europe and other geographies;
- the expected regulatory approval pathway for our therapeutic candidates;
- potential changes in regulatory requirements, and delays or negative outcomes from the regulatory approval process;
- our ability to maintain adequate quality processes and oversight of vendors
- our ability to secure raw materials to support continued drug substance and drug product manufacturing
- our reliance on third-parties for the planning, conduct, management and monitoring of clinical trials, for the manufacture of clinical drug supplies and drug product meeting our specifications, and for other requirements;
- our estimates of the size and characteristics of the markets that may be addressed by our therapeutic candidates;
- market acceptance of our therapeutic candidates that are approved for marketing in the United States or other countries;
- our ability to successfully commercialize our therapeutic candidates, if approved for marketing;
- the safety and efficacy of therapeutics marketed by our competitors that are targeted to indications which our therapeutic candidates have been developed to treat;
- our ability to utilize our proprietary technological approach to develop and commercialize our therapeutic candidates;
- our heavy dependence on licensed intellectual property, including our ability to source and maintain licenses from third-party owners;

- our ability to protect our own or in-licensed intellectual property and operate our business without infringing the intellectual property rights of others;
- our ability to attract, retain and motivate key personnel;
- our ability to generate revenue and become profitable;
- our reliance on third-party manufacturers to manufacture our drug substance and drug product that meets with our design specifications;
- our dependence on contract research organizations and other parties to manage our clinical trials;
- the outcome of our currently open Phase I/II clinical trial with TTX-MC138, which commenced in the third quarter of 2024, and our ability to complete this trial;
- the impact of natural disasters, global pandemics, armed conflicts and wars, labor disputes, lack of raw materials or other supplies, issues with facilities and equipment, or other forms of disruption to business operations at our manufacturing or laboratory facilities or those of our vendors;
- potential collaborations to license and commercialize any therapeutic candidates for which we receive regulatory approval in the future in or outside the United States; and
- other risks and uncertainties, including those listed under the caption "Risk Factors" in this Annual Report on Form 10-K and in our other regulatory filings.

The risks set forth above are not exhaustive. Other sections of this Annual Report on Form 10-K may include additional factors that could adversely affect our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for management to predict all risk factors, nor can we assess the impact of all risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements in this Annual Report on Form 10-K reflect our current views with respect to future events and with respect to our business and future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part II, Item 1A, "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You are advised, however, to consult any further disclosure we make in our reports filed with the U.S. Securities and Exchange Commission (the "SEC").

This Annual Report on Form 10-K may include data that we obtained from industry publications and third-party research, surveys and studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. This Annual Report on Form 10-K also may include data based on our own internal estimates and research, including estimates regarding our consolidated financial statements and business operations. Our internal estimates have not been verified by any independent source and, while we believe any data obtained from industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Such third-party data, as well as our internal estimates and research, are subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Part II, Item 1A, "Risk Factors" and elsewhere in this Annual Report on Form 10-K. These and other factors could cause our results to differ materially from those expressed in this Annual Report on Form 10-K.

This Annual Report on Form 10-K 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 Annual Report on Form 10-K is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report on Form 10-K may appear without the ®, TM or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

Summary of Material Risks

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

- risks related to our acquisition of Polynoma and its potential effects on our business and the price of our common stock and other securities, including our issuance to DEFJ of our Series A Preferred Stock and Series B Preferred Stock, which are not convertible until our stockholders approve the conversions thereof;
- risks related to our licensing agreement with Unleash including our issuance to Unleash of our Series C Preferred Stock, which is not convertible until our stockholders approve the conversion thereof;
- risks related to the potential issuance of our common stock pursuant to the SEPA with Yorkville and its potential effects on the price of our common stock and other securities;
- our low cash position and our estimates and expectations regarding our capital requirements, cash and expense levels, liquidity sources and our ability to obtain, on satisfactory terms or at all, the financing required to support operations, research, development, clinical trials, and commercialization of products;
- our business is highly dependent on the success of TTX-MC138, our lead therapeutic candidate which is at the early stages of development. Our therapeutic and diagnostic candidates require significant additional preclinical, clinical development and manufacturing validation before we may be able to seek regulatory approval for and launch approved products commercially;
- a potential delisting of our common stock from trading on the Nasdaq Capital Market if we do not comply with Nasdaq listing requirements;
- our ability to continue as a going concern;
- the results and timing of our preclinical and clinical trial activities, including but not limited to our ability to enroll a sufficient number of patients timely to advance our clinical trials;
- our ability to expand our therapeutic candidate portfolio through internal research and development or the acquisition or in-licensing of intellectual property assets;
- 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;
- potential changes in regulatory requirements, and delays or negative outcomes from the regulatory approval process;
- our reliance on third-parties for the planning, conduct, management and monitoring of clinical trials, for the manufacture of clinical drug substance and drug product that meets our specifications and for other requirements;
- market acceptance of our therapeutic candidates that are approved for marketing in the United States or other countries;
- our ability to successfully manufacture and 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;
- our ability to utilize our proprietary technological approach to develop and commercialize our therapeutic candidates;
- our heavy dependence on licensed intellectual property, including our ability to source and maintain licenses from third-party owners;
- our ability to protect our intellectual property and operate our business without infringing the intellectual property rights of others;
- our ability to attract, retain and motivate key personnel;
- our ability to generate revenue and become profitable;
- our ability to initiate and complete our clinical trials;

- our ability to arrange potential collaborations to license and commercialize any therapeutic candidates for which we receive regulatory approval in the future in or outside the United States;
- clinical development involves a lengthy, complex and expensive process, with an uncertain outcome, and the results of preclinical studies, manufacturing, 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, manufacturing and commercialization of TTX-MC138 or any of our other therapeutic candidates;
- quality problems could delay or prevent delivery of our materials for clinical trials or to the market;
- changes in methods of therapeutic candidate manufacturing or formulation may result in additional costs or delays;
- our therapeutic candidates may cause undesirable side effects or death or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences;
- if we are unable to advance our therapeutic candidates to clinical development, obtain regulatory approval and ultimately commercialize our therapeutic candidates or if we experience significant delays in doing so, our business will be materially harmed;
- even if we receive regulatory approval of TTX-MC138 or any of our other therapeutic candidates, we will be subject to ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements;
- 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 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;
- our ability to import drug product from outside the U.S. which may be expensive and require extensive regulatory approval resulting in potential delays in conducting clinical trials or commercial launch;
- ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and consolidated results of operations;
- we face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do;
- the price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock;
- we 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;
- 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 consolidated financial condition or consolidated results of operations, which may adversely affect our business and the trading price of our common stock, and
- other risks and uncertainties, including those listed under the caption “Risk Factors” in this Annual Report on Form 10-K and in our other regulatory filings.

Reverse Stock Splits

On May 23, 2023, we effected a reverse split of our common stock, either issued and outstanding or held by us as treasury stock, (the "2023 Reverse Split") previously approved by our board of directors (the "Board") and our stockholders. The 2023 Reverse Split was at a ratio of one share for every 20 shares previously held with no change in the par value per share. The 2023 Reverse Split did not change the number of authorized shares of common stock.

On January 16, 2024, we effected a reverse split of our common stock, either issued and outstanding or held by us as treasury stock, (the "January 2024 Reverse Split") previously approved by our Board and stockholders. The January 2024 Reverse Split was at a ratio of one share for every 40 shares previously held with no change in the par value per share. The January 2024 Reverse Split did not change the number of authorized shares of common stock.

On December 4, 2024, we effected a reverse split of our common stock, either issued and outstanding or held by us as treasury stock, (the "December 2024 Reverse Split") previously approved by our Board and stockholders. The December 2024 Reverse Split was at a ratio of one share for every 33 shares previously held with no change in the par value per share. The December 2024 Reverse Split did not change the number of authorized shares of common stock.

On May 15, 2025, we effected a reverse split of our common stock, either issued and outstanding or held by us as treasury stock, (the "May 2025 Reverse Split") previously approved by our Board and stockholders. The May 2025 Reverse Split was at a ratio of one share for every 28 shares previously held with no change in the par value per share. The May 2025 Reverse Split did not change the number of authorized shares of common stock.

All common stock share and per share data, and exercise price data for applicable common stock equivalents, included in our consolidated financial statements have been retroactively adjusted to reflect the 2023 Reverse Split, the January 2024 Reverse Split, the December 2024 Reverse Split, and the May 2025 Reverse Split.

PART I

Except where the context otherwise requires or where otherwise indicated, the terms "TransCode Therapeutics," "TransCode," "we," "us," "our," "our company," the "Company," and "our business" refer to TransCode Therapeutics, Inc.

ITEM 1. BUSINESS

Overview

TransCode is a clinical-stage company pioneering immuno-oncology and RNA therapeutics for treatment of high risk and advanced cancers. Our lead therapeutic product candidate is TTX-MC138, an antisense inhibitor of an oncogenic microRNA. TTX-MC138 has recently completed a Phase 1a clinical trial. In addition to other RNA-targeted product candidates, we are conducting research and development of a cancer vaccine product candidate and an oncolytic immunotherapy platform.

Polynoma Acquisition. On October 8, 2025, we entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") with DEFJ, LLC, a Delaware limited liability company, ("DEFJ") pursuant to which we acquired 100% of the issued and outstanding membership interests of ABCJ, LLC, a Delaware limited liability company, ("ABCJ") (such transaction, the "Acquisition"). In the Acquisition, we issued 1,152.9568 shares of our Series A Non-Voting Convertible Preferred Stock (the "Series A Preferred Stock") to DEFJ. Each share of Series A Preferred Stock is convertible into 10,000 shares of common stock. Prior to the Acquisition, ABCJ was a wholly owned subsidiary of DEFJ and an indirect wholly owned subsidiary of CK Life Sciences Int'l., (Holdings) Inc., a listed entity on the Main Board of the Hong Kong Stock Exchange.

ABCJ owns 100% of the issued and outstanding membership interests of Polynoma, LLC, a Delaware limited liability company, ("Polynoma") headquartered in San Diego, California. Polynoma is an immuno-oncology focused biopharmaceutical company developing Seviprotimut-L, an investigational polyvalent antigen vaccine intended to reduce the risk of recurrence of cancer in patients with stage IIB and IIC melanoma who have limited options. Seviprotimut-L has been safely administered in clinical trials to more than 1,000 patients.

We intend to work on developing both TTX-MC138 and Seviprotimut-L, with the initial focus on advancing TTX-MC138 in a planned Phase 2a clinical trial. We believe there is potential to augment Seviprotimut-L's focus with TTX-MC138 by addressing micrometastases in stage IIB and IIC melanoma patients and intend to conduct preclinical research combining seviprotimut-L and TTX-MC138 to explore potential synergies between the two compounds.

Concurrent with the Acquisition, we entered into an Investment Agreement (the "Investment Agreement") with DEFJ. Pursuant to the Investment Agreement, DEFJ agreed to purchase, and we agreed to issue and sell in a private placement, an aggregate of 223.7337 shares of Series B Non-Voting Convertible Preferred Stock, par value $0.0001 per share, (the "Series B Preferred Stock" and, together with the Series A Preferred Stock, the "Preferred Stock") for a price per share of $111,740, for an aggregate purchase price of approximately $25 million. The aggregate purchase price consisted of a cash subscription of $20 million paid on October 8, 2025, and a promissory note (the "Promissory Note") in the aggregate principal amount of approximately $5 million (together, the "Investment"). The Promissory Note accrued interest at a rate of 4% per annum, calculated as simple interest on a 365-day year. The principal and accrued interest were paid on December 30, 2025. Each share of Series B Preferred Stock is convertible into 10,000 shares of common stock.

Unleash License. On March 2, 2026, we entered into an Exclusive Licensing Agreement (the "Unleash Licensing Agreement") with Unleash Immuno Oncolytics, Inc., a Delaware corporation, ("Unleash") pursuant to which we acquired a pre-clinical candidate program involving genetically-engineered adenoviruses to harness the immune system to fight cancer, as well as an exclusive, perpetual, irrevocable, worldwide, fully-paid up, royalty-free, sublicensable right and license to related technology.

As consideration for the Unleash Licensing Agreement, pursuant to an Equity Issuance and Registration Rights Agreement with Unleash (the "Unleash Registration Rights Agreement"), we agreed to issue 1,136,364 shares of Series C Non-Voting Convertible Preferred Stock, par value $0.0001 per share, (the "Series C Preferred Stock") to Unleash. The Series C Preferred Stock is not convertible until our stockholders approve its conversion into shares of common stock in accordance with the listing rules of Nasdaq (the "Unleash Stockholder Approval"). Following the Unleash Stockholder Approval, each share of

Series C Preferred Stock is convertible into one share of our common stock. The powers, preferences, rights, qualifications, limitations and restrictions applicable to the Series C Preferred Stock are set forth in the Certificate of Designation of Preferences, Rights and Limitations of Series C Non-Voting Convertible Preferred Stock (the "Series C Certificate of Designation"). Pursuant to the Unleash Registration Rights Agreement, we agreed to file a registration statement registering the shares issued under the Unleash Registration Rights Agreement and to use commercially reasonable efforts to cause such registration statement to be declared effective by the SEC as soon as practicable after such registration statement is filed. We also granted Unleash customary demand registration and indemnification rights and entered into customary issuer covenants.

RNA Delivery Challenge

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 making available a broad array of previously undruggable targets in the human genome. We believe that a major limitation in using RNA as a therapeutic for cancer has been delivering it to tumors effectively. Our TTX platform, described in more detail below, is intended to overcome delivery issues of stability, efficiency, and immunogenicity faced by existing lipid and liposomal nanoparticle platforms while optimizing targeting of and accumulation in tumor cells and metastatic sites. The ability to deliver RNA therapeutics inside tumors and metastases gives us the potential to target genes of importance for cancer treatment that, until now, have remained undruggable using an RNA approach. 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.

Proprietary TTX Drug Design Engine

The therapeutic potential of RNA in oncology remains an unrealized promise due, we believe, to the difficulty in safely and effectively delivering oligonucleotides to tumors. We have created a design engine to customize the development of RNA therapeutics that we believe brings us closer to solving this challenge. This engine, which we call TTX, is modular, both at the levels of the core delivery vehicle and with respect to therapeutic loading. The size, charge, surface chemistry, conjugation chemistry, and payload can be selected to meet desired PK, PD, and tissue targeting specifications thus optimizing (i) delivery to the intended genetic target and (ii) the therapeutic load. The therapeutic load, consisting of synthetic oligonucleotides, can also be adapted to the specific approach being developed. Approaches can include RNA interference, or RNAi, such as small interfering RNAs, or siRNAs, and non-coding RNA mimics. Other approaches can include antisense oligonucleotides, or ASOs, as well as Pattern Recognition Receptors such as RIG-I. Our TTX platform can further be used for developing radioligand, small molecule, antibody, peptide, or protein-based therapeutics and other custom products targeting known and novel biomarkers and other genetic elements as they are discovered and validated. TTX has been used successfully to deliver oligonucleotide, peptide, small molecule, radioligand, and protein payloads to cancer cells in preclinical animal models. Further, TTX has also been used to deliver oligonucleotide payloads to macrophages in multiple organs, including lungs, liver, lymph nodes, and tumors. We believe our TTX drug design engine can be effective in developing treatments for cancer and pathologies related to macrophage dysfunction.

We believe that demonstrating our ability to overcome the challenge of RNA delivery to genetic targets outside of 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. Based on our clinical and preclinical experience, we expect our competitive advantages to include effectively reaching tumors and metastases, achieving robust target engagement in tumor cells, and offering an anticipated wide therapeutic window.

Modular Design Toolbox

Our TTX approach is based on four complementary elements that we believe together address the challenges of RNA drug development in oncology:

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 specific oligos that correspond

to genetic targets of interest. Once we determine the code of the cancer target, we can develop therapeutic candidates using specific oligos 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; 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 therapeutics with tunable chemistry properties. 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.

Delivery — Our strategy seeks to leverage a modular carrier that can be tailored in terms of size, charge, conjugation chemistry, payload release mechanism and kinetics, in order to meet predesigned PK, PD, biodistribution, and tissue targeting. This delivery technology differentiates us from competitive delivery approaches, many of which rely on lipid particles or chemical structures, such as GalNAc. Competitive delivery approaches effectively target sites in the liver but not sites in tumors and metastases. Our carrier is optimized for targeting cancer cells and macrophages.

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 the 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.

Lead RNA Program

Our lead therapeutic candidate, TTX-MC138, targets microRNA-10b, or miR-10b, a master regulator of metastatic cell viability in a range of cancers, including breast, pancreatic, ovarian, colon, glioblastomas, and several others.

In 2023, we conducted a Phase 0 clinical trial using a microdose of a radiolabeled form of TTX-MC138 called TTX-MC138-NODAGA-Cu64. The trial was designed to demonstrate quantitative delivery of TTX-MC138 to metastatic lesions in subjects with advanced solid tumors. On May 29, 2024, we announced preliminary data from the patient enrolled in the Phase 0 clinical trial suggesting effective targeting of metastatic lesions and pharmacodynamic activity in blood, even at a microdose. The results from the patient dosed in the Phase 0 clinical trial indicated that a microdose of radiolabeled TTX-MC138 resulted in significant inhibition of the drug candidate's molecular target, miRNA-10b, in the patient's blood. Specifically, after injection, the amount of miR-10b in the patient's blood at 24 hours following dosing was approximately 66% lower than levels prior to administration of radiolabeled TTX-MC138. We believe these data support our belief that clinical development of TTX-MC138 has the potential for clinical benefit in patients with metastatic cancer. In addition, the Phase 0 clinical trial also quantified the amount of drug candidate delivered to metastatic lesions, providing further indication that TTX-MC138 accumulated in metastatic tumors. The increase of radioactive lesion-to-blood ratios suggests that circulating TTX-MC138 is actively taken up by cancerous tissue. Overall, the microdose of radiolabeled TTX-MC138 was well tolerated with no adverse events observed. The clinical study report has been completed and results shared at a scientific meeting.

In the second half of 2024, we commenced a Phase 1a clinical trial designed as an open-label, multicenter study in cancer patients with advanced solid tumors. The objectives of this trial were to evaluate the safety and tolerability of escalating dose levels of TTX-MC138 to determine its maximum tolerated dose, or MTD, from which we anticipated selecting a recommended Phase 2 dose, or RP2D, level. On October 14, 2025, we announced completion of this trial, that the trial had met the primary endpoint of safety, and the decision to move forward into the next stage of clinical evaluation of TTX-MC138.

In the Phase 1a trial, 16 patients were treated using four escalating dose levels. No significant treatment-related safety events or dose-limiting toxicities were observed and there were positive pharmacodynamic effects over all four dose levels, consistent with preclinical models and our Phase 0 clinical trial results. Key assessments in the clinical trial are to characterize TTX-MC138's safety, pharmacokinetic, pharmacodynamic and anti-tumor activity thus identifying an MTD and ensuring the mechanism of action is on target. The clinical trial also is exploring the effect of TTX-MC138 on biomarker expression, which may include miR-10b expression, and miR-10b downstream targets (RNA sequencing). Clinical assessments to further evaluate TTX-MC138 include clinical laboratory exams, CT scan assessments, and response assessments per RECIST criteria. We believe that results from the Phase 1a trial support advancement to a Phase 2a clinical trial with the treatment dose selected based on the Phase 1a results.

On December 11, 2025, we announced a new collaboration to evaluate TTX-MC138 as part of the PRE-I-SPY clinical trial platform operated by Quantum Leap Health Care Collaborative ("Quantum Leap"). The PRE-I-SPY program will incorporate TTX-MC138 into a Phase 2a clinical trial designed as a multicenter, open-label, dose-expansion trial treating patients for one year with one year of post-treatment follow-up. The trial will evaluate event-free survival, ctDNA dynamics and pharmacokinetics of TTX-MC138 in up to 45 patients with stage I-III adenocarcinoma of the colon or rectum, who are ctDNA positive with minimal residual disease detected by tumor-informed ctDNA assays, who have completed standard curative-intent therapy, and who show no radiographic evidence of recurrence or metastasis. This trial is planned to begin in the second quarter 2026 and will be led by Principal Investigator Dr. Paula Pohlmann of the MD Anderson Cancer Center. The study is being conducted under a Quantum Leap IND and cross-referenced to our IND.

Other RNA Programs

Our preclinical RNA programs include TTX-siPDL1, an siRNA-based modulator of programmed death-ligand 1, or PD-L1, and two indication-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; and TTX-siMYC, an siRNA-based MYC inhibitor.

Seviprotimut-L

Seviprotimut-L, the Polynoma product candidate in development for the adjuvant treatment of patients with Stages IIB and IIC melanoma, is a polyvalent vaccine derived from three human melanoma cell lines. It is intended for patients with high-risk melanoma who have undergone surgery. Seviprotimut-L has received Fast Track designation from the FDA for its potential to treat melanoma. A Phase III clinical trial has completed its dose evaluation and preliminary efficacy; preliminary data have been encouraging in certain patient subgroups such as those under age 60 and those with specific types of primary melanomas.

We intend to evaluate a combination treatment of TTX-MC138 and Seviprotimut-L in a preclinical program. The program aims at exploring potential synergies between both compounds to address metastatic disease. While there is no prior experimental evidence that any such synergies exist, we believe that testing TTX-MC138 in combination with a cancer vaccine is justified based on the known immunomodulatory roles of miR-10b, the target for TTX-MC138. Specifically, miR-10b has been shown to inhibit MICB, a ligand of NKG2D, which thus inhibits tumor cell killing by natural killer, or NK, cells. Roles for miR-10b in checkpoint inhibition have also been described in the literature. Notably, in murine models of glioblastoma, miR-10b inhibition activated antitumor immune responses, increased cytotoxic CD8+ T cells infiltration, and promoted durable immune memory, enabling tumor rejection upon rechallenge.

Oncolytic Immunotherapy Platform

Under the Unleash Licensing Agreement, we acquired rights to three compounds, UIO 524, UIO 525 and UIO 526, that we believe complement and expand our oncology pipeline. These compounds comprise a next-generation, biology-driven oncolytic immunotherapy platform designed to address solid tumor indications with high-unmet medical needs, beginning with muscle-invasive bladder cancer (MIBC). MIBC is a significant unmet medical need with poor outcomes, limited durable treatment options, and a highly immunosuppressive tumor microenvironment. Bladder cancer overall represents a multi-billion-dollar global market, with muscle-invasive disease accounting for a disproportionate share of treatment intensity and healthcare costs, creating what we believe is a compelling opportunity for differentiated therapeutic approaches.

UIO-524, the lead Unleash candidate, is a rationally-designed oncolytic adenovirus engineered to selectively replicate within both malignant cells and cancer-associated stroma. The virus delivers a multi-cytokine immune-activating payload comprising CD40-L, 4-1BBL, and IL-21, intended to activate dendritic cells, T cells, and NK cells, and to drive a robust, systemic anti-tumor immune response. UIO-524 is regulated by a proprietary SPARC promoter that is highly active in malignant cells and cancer-associated stromal compartments and which enables biology-driven differentiation. This design enables selective viral replication and localized expression of immune-activating cytokines within the tumor microenvironment.

UIO-524 builds on CG Oncology's CG0070, the most clinically advanced and successful oncolytic adenovirus to date, demonstrating meaningful activity in non–muscle-invasive bladder cancer (NMIBC). UIO-524 contains a structurally-related oncolytic adenovirus backbone, incorporates tumor- and stroma-targeted replication, and contains a more comprehensive, multi-cytokine immune payload. This design positions UIO-524 as a next-generation oncolytic immunotherapy candidate intended to address more aggressive diseases such as MIBC.

MD Anderson Cancer Center Alliance

In late 2024, we and The University of Texas M. D. Anderson Cancer Center ("MD Anderson") agreed to amend our five-year strategic collaboration agreement in favor of MD Anderson focusing solely on participation in our Phase I/II clinical trial. This amendment relieved us from the obligation to make up to $10 million of collaboration payments. We are obligated to pay charges incurred by MD Anderson in connection with clinical trial services.

TTX-MC138

Our scientific co-founders developed our initial therapeutic candidate while on staff at The General Hospital Corporation, d/b/a Massachusetts General Hospital, or MGH. They designed TTX-MC138 to leverage our TTX drug design engine using antisense technology to target microRNA-10b, or miR-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 of, we believe, challenges in delivering nucleic acids to tumors despite microRNA-10b's strong association with cancer metastasis as documented in over 700 peer-reviewed scientific publications deposited on PubMed that refer to miR-10b.

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 existing 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 in which human metastatic breast cancer cells had been implanted. 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 TTX- MC138 because doxorubicin slows metastatic cell replication specific to these tumor models. Doing so allowed TTX-MC138 to inhibit the targeted RNA (miR-10b) inside the tumor cells more efficiently.

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 representing 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.

In 2023, we conducted a FIH clinical trial with TTX-MC138-NODAGA-Cu^{64} (a radiolabeled version of TTX-MC138). Trial subjects were to receive a single injection of a microdose of TTX-MC138-NODAGA-Cu^{64}, followed by imaging by integrated positron emission tomography-magnetic resonance imaging, or PET-MRI. The Phase 0 trial 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. One patient was dosed in the Phase 0 trial. On May 29, 2024, we announced new preliminary data from the Phase 0 clinical trial suggesting anti-tumor activity. The new results from the patient dosed in the Phase 0 clinical trial indicate that a microdose of radiolabeled TTX-MC138 resulted in significant inhibition of the drug candidate's molecular target, miRNA-10b, in the patient's blood. Specifically, after injection, the amount of miR-10b in the patient's blood at 24 hours following dosing was approximately 66% lower than levels prior to administration of radiolabeled TTX-MC138. We believe these data support our belief that clinical development of TTX-MC138 has the potential for clinical benefit in patients with metastatic cancer. In addition, the Phase 0 clinical trial also quantified the amount of drug candidate delivered to metastatic lesions, providing further indication that TTX-MC138 accumulated in metastatic tumors. The increase of radioactive lesion-to-blood ratios suggests that circulating TTX-MC138 is actively taken up by the cancerous tissue. Overall, the microdose of radiolabeled TTX-MC138 was well tolerated with no adverse events observed. We are preparing the study's final report and plan to publish the complete results.

In April 2024, we received an Investigational New Drug "Study May Proceed" letter from the FDA to conduct a Phase I/II clinical trial with TTX-MC138. The Phase I/II clinical trial is an open-label, multicenter study in cancer patients with advanced solid tumors. The objectives of this trial are to evaluate safety and tolerability of escalating dose levels of TTX-MC138. The objective of the dose-escalation stage of the trial is to determine the maximum tolerated dose, or MTD, of TTX-MC138 from which we anticipate selecting a recommended Phase 2 dose, or RP2D, level. On September 17, 2024, we announced the dosing of the first patient in the Phase I/II clinical trial. On October 10, 2024, we announced completion of the initial dosing of the first cohort's three patients, and, on October 23, 2024, we announced receipt of the clinical trial's Safety Review Committee's authorization to proceed with dosing the second patient cohort. On January 14, 2025, we announced dosing the first patient in Cohort 3 of the clinical trial. On February 6, 2025, we announced completion of the initial dosing of Cohort 3. On March 13, 2025, we announced the Safety Review Committee's approval to begin dosing the fourth cohort of the clinical trial. We announced the initial dosing of the first patient in Cohort 4 on March 27, 2025. Key assessments in the clinical trial characterize the safety, pharmacokinetic, pharmacodynamic and anti-tumor activity thus identifying a maximum tolerated dose (MTD) and ensuring the mechanism of action is on target. The study is also exploring the effect of TTX-MC138 on biomarker expression, which may include miR-10b expression, and miR-10b downstream targets (RNA sequencing). Clinical assessments to further evaluate TTX-MC138 include clinical laboratory exams, CT scan assessments, and response assessments per RECIST.

Polynoma Acquisition and CK Life Sciences Strategic Financing

Membership Interest Purchase Agreement

On October 8, 2025, we entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") with DEFJ, LLC, a Delaware limited liability company, ("DEFJ") pursuant to which we acquired 100% of the issued and outstanding membership interests of ABCJ, LLC, a Delaware limited liability company ("ABCJ" and such transaction, the "Acquisition"). Prior to the Acquisition, ABCJ was a wholly owned subsidiary of DEFJ and an indirect wholly-owned subsidiary of CK Life Sciences Int'l., (Holdings) Inc. ("CKLS"), a listed entity on the Main Board of the Hong Kong Stock Exchange.

Under the terms of the Purchase Agreement, upon consummation of the Acquisition, which occurred concurrently with the execution of the Purchase Agreement (the "Closing"), in exchange for all of the membership interests of ABCJ outstanding immediately prior to the Closing, we issued to DEFJ an aggregate of (i) 83,285 shares of our common stock, par value $0.0001 per share, ("Common Stock") which shares represented 9.99% of the shares of our Common Stock outstanding immediately

prior to the Closing, and (ii) 1,152.9568 shares of our Series A Preferred Stock (as described below). In addition, we agreed to make up to $95 million in contingent milestone payments to DEFJ upon the achievement of certain milestones. Each share of Series A Preferred Stock is convertible into 10,000 shares of Common Stock. The powers, preferences, rights, qualifications, limitations and restrictions applicable to the Series A Preferred Stock are set forth in the Certificate of Designation (as defined and described below). The Acquisition is intended to be treated as a taxable exchange for U.S. federal income tax purposes.

Investment Agreement

Concurrent with the Acquisition, on October 8, 2025, we entered into an Investment Agreement (the "Investment Agreement") with DEFJ. Pursuant to the Investment Agreement, DEFJ agreed to purchase, and we agreed to issue and sell in a private placement, an aggregate of 223.7337 shares of Series B Preferred Stock for a price per share of $111,740 or an aggregate purchase price of approximately $25 million. The aggregate purchase price comprised a cash subscription of $20 million and a promissory note (the "Promissory Note") in the aggregate principal amount of approximately $5 million (the "Investment"). The Promissory Note accrued interest at a rate of 4% per annum, calculated as simple interest on a 365-day year. The principal and accrued interest were paid on December 30, 2025. Each share of Series B Preferred Stock is convertible into 10,000 shares of Common Stock. The powers, preferences, rights, qualifications, limitations and restrictions applicable to the Series B Preferred Stock are set forth in the Certificate of Designation.

Approvals

Our Board unanimously approved the Purchase Agreement, the Investment Agreement and the related transactions. The consummation of the Acquisition and the Investment was not yet subject to approval by our stockholders. Pursuant to the Purchase Agreement, we have agreed to hold a stockholders' meeting to submit the following matters to stockholders for their consideration: (i) the approval of the conversion of the shares of Series A Preferred Stock and Series B Preferred Stock into shares of Common Stock in accordance with the rules of the Nasdaq Stock Market LLC (the "Conversion Proposal") and (ii) the approval of a "change of control" under Nasdaq Listing Rules 5110 and 5635(b) (the "Change of Control Proposal" and, together with the Conversion Proposal, the "Meeting Proposals"). In connection with these matters, we have agreed to file a proxy statement on Schedule 14A with the SEC.

Descriptions Qualified

The foregoing descriptions of the Acquisition, the Investment, the Purchase Agreement and the Investment Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the Purchase Agreement and Investment Agreement, copies of which are filed as Exhibit 2.1 and Exhibit 10.13, respectively, to this Annual Report on Form 10-K and are incorporated herein by reference.

The Purchase Agreement and the Investment Agreement have been filed herewith to provide investors and securityholders with information regarding their terms. They are not intended to provide any other factual information about us, on the one hand, or DEFJ, ABCJ or OpCo (as defined in the Purchase Agreement), on the other hand. The Purchase Agreement and the Investment Agreement contain representations, warranties and covenants that we and DEFJ made to each other as of specific dates. The assertions embodied in those representations, warranties and covenants were made solely for purposes of the Purchase Agreement and the Investment Agreement between us and DEFJ and may be subject to important qualifications and limitations agreed to by us and DEFJ in connection with negotiating their terms, including being qualified by confidential disclosures exchanged between the parties in connection with the execution of the Purchase Agreement and the Investment Agreement. Further, the representations and warranties may be subject to a contractual standard of materiality that may be different from what may be viewed as material to investors or securityholders. Moreover, information concerning the subject matter of the representations and warranties may change after the date of the Purchase Agreement and the Investment Agreement, which subsequent information may or may not be fully reflected in our public disclosures.

Our Pipeline

We plan to continue research on a variety of microRNAs and biomarkers involved in cancer cell proliferation, carcinogenesis and metastasis. Our lead candidate, TTX-MC138, entered its first phase of clinical assessment in August 2023. We may request various FDA designations or approvals including Breakthrough Therapy, Accelerated Approval, Priority

Review and Fast Track Designation based on clinical development results, and Orphan Disease Designation as many cancer indications are classified as orphan diseases. In addition, we amended our worldwide exclusive license with MGH to include a small interfering RNA, or siRNA, therapeutic candidate against PD-L1 in pancreatic and other cancer types including melanoma, breast and non-small cell lung cancer. This technology was invented at MGH by one of our scientific co-founders. We recently evaluated the efficacy of TTX-MC138 applied as monotherapy in a murine model of pancreatic adenocarcinoma. In this study, we treated mice bearing human pancreatic tumors implanted in their pancreata with TTX- MC138 once weekly for eight weeks. The candidate demonstrated a pharmacodynamic response by successfully inhibiting its target, microRNA-10b (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. Metastatic burden in these animals was inhibited by approximately 50% compared to animals treated with gemcitabine, the current standard of care.

In connection with the Acquisition, we obtained the clinical program for Seviprotimut-L, a novel polyvalent shed antigens vaccine for the adjuvant treatment of Stage IIB and IIC melanoma patients 60 years and younger. Seviprotimut-L has completed Phase 2 clinical development.

Through the Unleash Licensing Agreement, we obtained rights to an immuno-oncolytic therapeutic platform and are exploring developing agents that directly target tumors while simultaneously stimulating systemic immune responses. This platform expands our reach into novel mechanisms of action and enables the creation of differentiated, next-generation cancer therapies, initially focusing on muscle-invasive bladder cancer (MIBC).

Our Proprietary Delivery Engine, TTX, underpins multiple programs and is designed to (i) improve precision and targeting, (ii) enhance therapeutic index, and (iii) enable flexible payload and therapeutic modality development. We are in early preclinical stages with all but two of our therapeutic candidates.

We also intend to conduct a preclinical evaluation of a combination treatment using TTX-MC138 and Seviprotimut-L. The program aims at exploring potential synergies between both compounds to address metastatic disease. While there is no prior experimental evidence that any such synergies exist, we believe that testing TTX-MC138 in combination with a cancer vaccine is justified based on the known immunomodulatory roles of miR-10b, the target for TTX-MC138. Specifically, miR-10b has been shown to inhibit MICB, a ligand of NKG2D, which thus inhibits tumor cell killing by natural killer, or NK, cells. Roles for miR-10b in checkpoint inhibition have also been described in the literature. Notably, in murine models of glioblastoma, miR-10b inhibition activated antitumor immune responses, increased cytotoxic CD8+ T cells infiltration, and promoted durable immune memory, enabling tumor rejection upon rechallenge.

The following table summarizes our development pipeline:

Received orphan designation status from FDA for Sevipotimut-L and for PDAC with TTX-MC138 and TTX-siPDL1

RNA Background

RNA has long been viewed as an attractive therapeutic modality because it can be used to target a wide array of diseases; it involves rational and straightforward drug design, the drugs are highly selective for their target, and nominal amounts of drug are required to achieve powerful therapeutic activity. In addition, such drugs have the ability to engage targets that are otherwise 'undruggable' by targeted therapeutics, such as small molecules and monoclonal antibodies, thus opening up whole new avenues for treating intractable diseases. Turning this concept into a clinical reality, however, is no small feat. Therapeutic nucleic acids, such as mRNA, ASOs and siRNAs have been in clinical development for decades, and for much of this time, clinical success has been out of reach. This lack of clinical success is due to three delivery-related challenges:

1. protecting the therapeutic oligonucleotide from dismantling by the immune system,

2. maintaining stability long enough to allow for full therapeutic effect on the tumor, and

3. penetrating the target organs and cells.

Because of these challenges, RNA as a cancer treatment modality has been bypassed largely by the interest in other forms of treatment including immunotherapy. One enticing feature of RNA-targeting therapeutics is that once chemistry and delivery are optimized, designing and producing a lead compound for a new target based on the TTX design engine is relatively straightforward, and their *in vivo* pharmacokinetic profiles are highly predictable. This means that the timeline from target identification to preclinical proof of concept in animal models should be measurable in months rather than years, more often the norm for drug development. This is reflected in a burgeoning industry clinical pipeline: currently more than a hundred investigational RNA-targeting drugs are under clinical development for disease indications encompassing neurodegeneration, metabolic and cardiovascular disorders and various cancers. Advancements in the field are now accelerating after years of slow progress. In 2016, nusinersen, a splice-switching ASO, was approved by the FDA and became the first oligonucleotide drug to treat spinal muscular atrophy, a rare and often fatal disease of the nervous system, and 2018 witnessed the first ever approval of an RNAi drug — patisiran — to treat polyneuropathy of hereditary transthyretin-mediated amyloidosis, another rare and devastating disease mediated by the liver. These successes validated the clinical utility of RNA-targeting therapeutics and brought forward lifesaving drugs for patients who previously had no effective treatment options.

Our scientific approach is based on three complementary elements that address these challenges: the ability to precisely deliver an oligonucleotide to an RNA target without compromising the integrity of the oligonucleotide; a platform on which to develop oligonucleotides that are designed to attack specific disease-causing RNA targets; and an imaging capability for optimal targeting which can guide therapeutic intervention.

Our scientific co-founders initially developed the lead therapeutic candidate while at MGH to address the challenge of targeting microRNA-10b, a well validated target linked to metastatic cancer, which has been shown to cause up to approximately 90% of all cancer deaths. In contrast, most anti-cancer therapies target primary tumors and do not address metastatic disease specifically. So far, no effective therapeutic has been developed to target microRNA-10b because of the delivery challenges despite microRNA-10b's strong association with cancer metastasis. MiRNA-10b is a well validated disease target as documented in over 800 scientific publications deposited on PubMed that refer to miR-10b.

TTX Drug Design Engine

The therapeutic potential of RNA in oncology remains an unrealized promise due, we believe, to the difficulty in safely and effectively delivering oligonucleotides to tumors. We believe we are now closer to solving this challenge by means of our proprietary TTX drug design engine.

TTX has been used successfully to deliver oligonucleotide, peptide, small molecule, radioligand, and protein payloads to cancer cells in preclinical animal models. In addition, TTX has been used to deliver oligonucleotide payloads to macrophages in multiple organs, including lungs, liver, lymph nodes, and tumors. The TTX design engine can be tailored in terms of size, charge, surface coating, conjugation chemistry, and payload to meet desired PK, PD, and tissue targeting specifications. The TTX drug design engine is envisioned for the treatment of cancer and pathologies related to macrophage dysfunction. We believe that another advantage of our TTX platform is the ability to use noninvasive MRI-monitoring of delivery of the therapeutic candidate to target tissues. We believe

that this advantage represents an indispensable tool to assess and control delivery to targeted tissues which has the potential to enhance the clinical development program. Our most advanced program focuses on metastatic cancers, which have been shown to be responsible for up to approximately nine million deaths per year worldwide. In preclinical studies in metastatic breast cancer and pancreatic cancer models in mice, our lead therapeutic candidate demonstrated the ability to be delivered to existing tumors and metastatic lesions and demonstrated complete regression without recurrence of metastasis during the study periods.

In one preclinical study using a stage II/III breast cancer model, our lead therapeutic candidate elicited complete regression without recurrence during the 12-week study period and 100% survival in the treated animals. In another preclinical study using an aggressive stage IV cancer model, our lead therapeutic candidate elicited complete regression without recurrence during the study period in 65% of animals treated. In a third preclinical study in an aggressive pancreatic cancer model, our lead therapeutic candidate inhibited metastatic disease by approximately 50% relative to animals treated with gemcitabine. At the end of the study, only 40% of the animals treated with TTX-MC138 had evidence of metastasis compared to 80% for animals treated with gemcitabine.

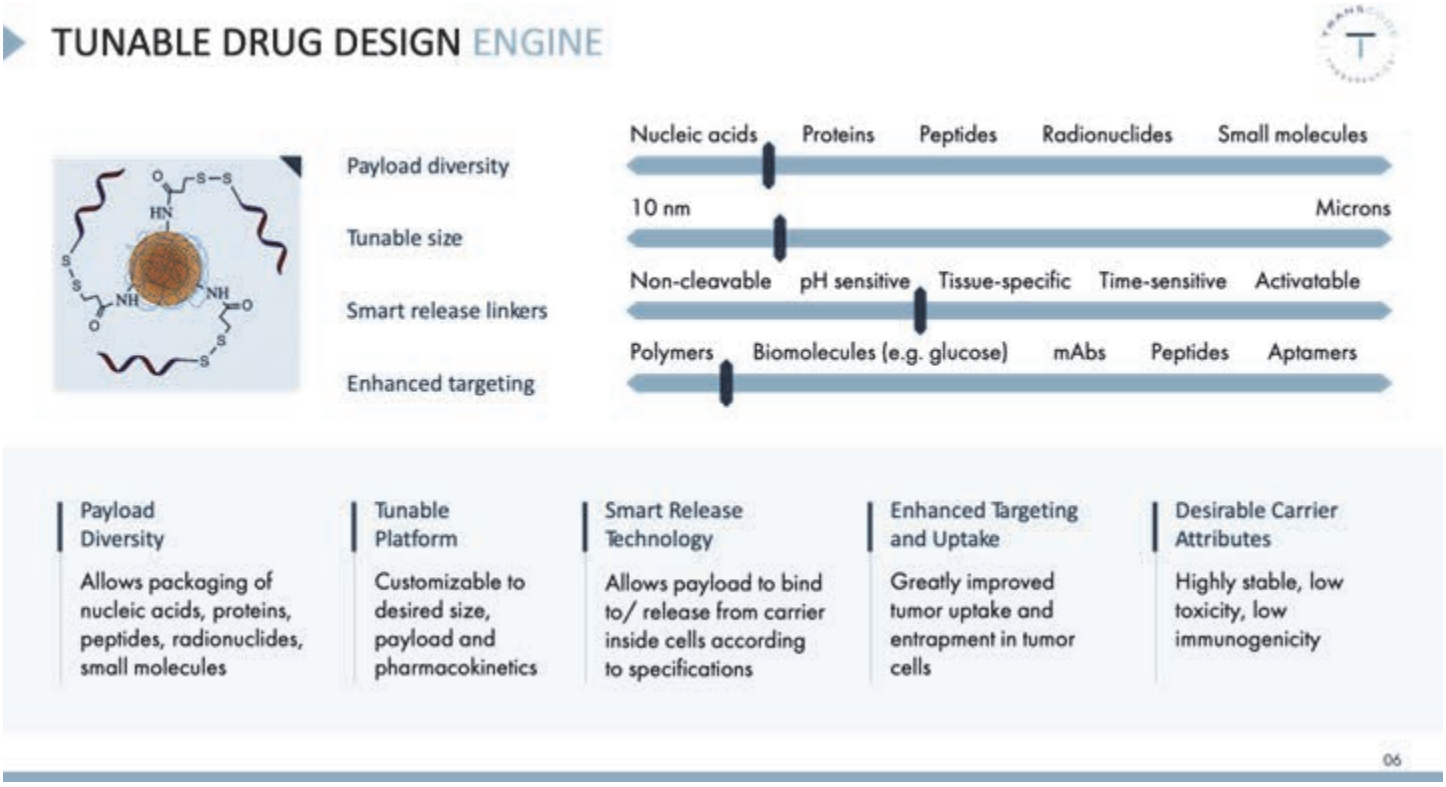

Figure 1. *Tunable Drug Design Engine*

The general design of our drug design engine is described in **Fig. 1.** The drug design engine, TTX, has been optimizedfor delivery to primary and metastatic tumors. Based on the literature and our own studies, we believe that the delivery of TTX-candidates to tumors and metastases relies on a combination of hemodynamic, physicochemical and metabolic factors. Our therapeutic candidates distribute to the interstitium (spaces between cells) of tumors and metastases via the enhanced permeability and retention, or EPR, effect, followed by uptake into tumor cells. Tumor cell uptake is also driven by the high metabolic activity of cancer cells, a mechanism that has been used widely in the clinic for tumor detection and staging using noninvasive nuclear imaging. An additional advantage of our design derives from the capability for noninvasive imaging via magnetic resonance imaging, or MRI, resulting from the chemical design of TTX.

The TTX delivery platform is highly differentiated from other oligonucleotide delivery systems that have been developed commercially **(Fig. 2)**.

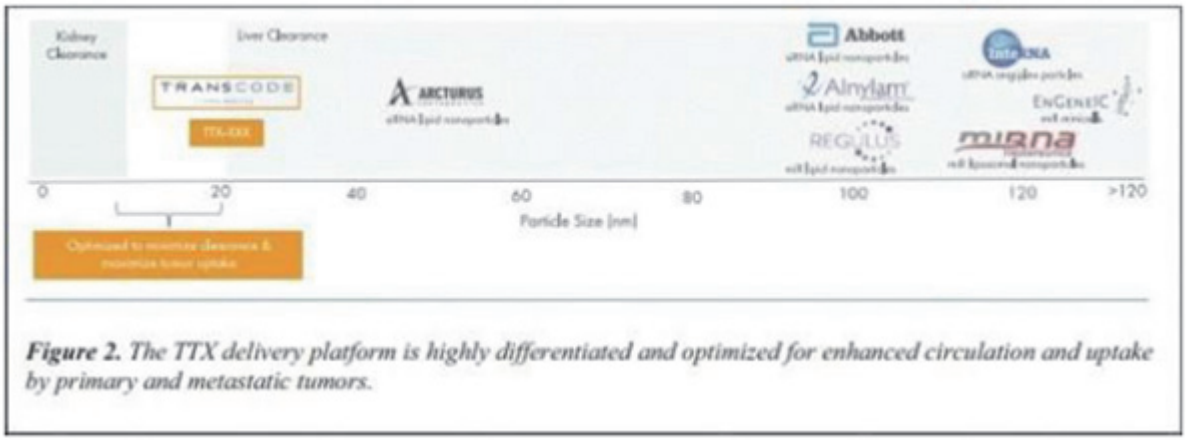

Figure 2. *The TTX delivery platform is highly differentiated and optimized for enhanced circulation and uptake by primary and metastatic tumors.*

TTX offers the following advantages:

- Small size (20-30 nanometers) gains access to tumors and metastases and avoids early clearance by the liver and kidneys; long circulation half-life;
- Low risk of immunogenicity vs competitor lipid particles which have been shown to induce undesirable immune responses via a number of different mechanisms, including complement activation and inflammatory cytokine overproduction;
- Quantitative noninvasive imaging via MRI and measurement of drug bioavailability during treatment;
- Surface coating creates steric hindrance by blocking large nuclease proteins from gaining access to oligonucleotides and results in improved stability and cell uptake;
- Highly stable, low toxicity potential; and
- Accumulation inside tumors and metastases as well as greater binding affinity and specificity to intended genetic targets inside tumor cells.

Preclinical Proof of Delivery

In our preclinical studies, we used our lead therapeutic, TTX-MC138, which is designed to specifically target miRNA-10b. The therapeutic candidate which was fluorescently labeled was injected into mice implanted with a murine breast cancer cell line. In this model, orthotopically implanted (breast area) tumors progress from localized disease to lymph node, lung, and bone metastases by 10 days after tumor inoculation. Optical imaging performed 24 hours after intravenous injection of TTX-MC138 revealed uptake by the metastatic lesions in the lymph nodes, lungs, and bone. Fluorescence microscopy confirmed widespread uptake by the metastatic tumor cells in these organs supporting our hypothesis that the therapeutic candidate, as designed can target disseminated cancer to distant organs. In addition to demonstrating delivery, we have also observed efficient target engagement. We analyzed the expression of the miRNA-10b target in a mouse model treated with TTX-MC138 and observed abolition of the target.

TTX-MC138

Metastatic cancer is cancer which has spread from an original tumor location to new sites in the body. Treatment of metastatic cancer is more complicated than treating early-stage cancer. Most treatments for metastatic cancer are focused on providing palliative care.

With increases in the prevalence of disease and in life expectancy, there is also a rise in R&D expenditures in the field of oncology. According to Maximize March Research, the metastatic cancer treatment market size was $83.85 billion in 2023. This market is expected to reach $137.31 billion in 2030, representing a compounded annual growth rate of 7.3% over that period. Rising prevalence of cancer and high unmet medical needs of patients suffering from metastatic cancer are the drivers stimulating the growth of the metastatic cancer treatment market.

We are developing TTX-MC138 for the treatment of metastatic cancer. TTX-MC138 targets the validated critical driver of metastatic progression, microRNA-10b. We believe that TTX-MC138 has the potential to improve outcomes over treatment alternatives currently available as well as other drugs currently in development, which are geared towards treating primary cancer but are of limited efficacy treating disseminated malignancy. In preclinical studies of animals with metastatic lesions, TTX-MC138 was successfully delivered to those lesions, eliminated metastasis in the animals and elicited complete regression without recurrence, resulting in 100% survival of subjects treated in a stage II/III cancer model and 65% survival of subjects treated in a very aggressive stage IV cancer model.

MicroRNA-10b (miR-10b)

One of the first miRNAs to be shown as having aberrant expression in cancer was miR-10b. Since the inaugural study on miR-10b in Dr. Robert Weinberg's lab at the Whitehead Institute for Biomedical Research and Department of Biology, Massachusetts Institute of Technology, its role as a metastasis promoting factor has been extensively validated. To date, more than 700 studies have been published on miR-10b and cancer across at least 18 different cancer types. This immense set of information holds possibilities for novel methods to improve the lives of many. The therapeutic target, miRNA, is a regulatory RNA. MiRNAs are placed at the apex of the gene regulatory pyramid and play a fundamental role in defining cell fate. Therefore, we believe by targeting microRNAs, it may be possible to achieve a persistent therapeutic response in cancer patients. Our hypothesis is based on the rationale that the tumor cell phenotype is critically dependent on fundamental molecular pathways of oncogenesis and that altering these pathways can result in very specific and robust therapeutic effects. The miRNA genome is a target because it is uniquely altered in tumor cells and represents a "hub" of carcinogenesis, since a single microRNA can coordinately affect the expression of multiple genes resulting in a comprehensive therapeutic response. In addition, because of the fundamental role played by microRNAs in defining tumor cell phenotypes, evasion of this therapeutic intervention by mutation is less likely. Underscoring the potential importance of microRNAs in health and disease, the 2024 Nobel Prize in Medicine was awarded for their discovery.

Metastatic cells are uniquely capable of leaving the primary tumor, surviving in circulation and colonizing a distant organ which has properties distinct from the primary tumor where the cells originated. Cells endowed with this capability evolve in response to an adaptive process driven by a cellular "survival instinct." Specifically, as tumors proliferate, pockets arise inside them characterized by inadequate resource supply due to failure of the tumor vasculature to keep up with the rapidly increasing tumor cell burden. This generates local inhospitable areas of low pH, high inflammation, and insufficient stromal supportive network necessary to maintain the survival of the tumor cells. As a result, some of the tumor cells within these pockets evolve by activating mechanisms, such as those driven by high miR-10b expression, that allow them to survive in the absence of abundant nutrient supply and to persist without the strong attachment to the extracellular matrix. These newly emergent cells become "refugees" from the primary tumor, invisible to most diagnostic/imaging modalities and resistant to most currently available therapeutic modalities. In our search for the ideal therapeutic target, our co-founders identified microRNA-10b as critical for the survival of these cells. Our lead candidate is designed to enter these tumor cells and inhibit miR-10b. Without the high level of expression of miR-10b, these cells, stripped out of their natural microenvironment, do not have the adaptive mechanism they need in order to survive, so they simply die.

Preclinical and clinical evidence of miR-10b's role in cancer

Against this conceptual framework, we have designed our lead therapeutic-candidate, TTX-MC138, which is designed with the potential to efficiently inhibit microRNA-10b in metastatic cancers. Studies in mouse models implanted with human metastatic breast cancer concluded that weekly treatment with TTX- MC138 in combination with low-dose chemotherapy was the likely reason for regression of established metastatic lesions in the lymph nodes, as well as distant organs such as the lungs and bone. Once disappearance of the metastatic lesions was observed in treated subjects with stage II, III and IV cancer models, treatment of the animals was stopped, and they were monitored for recurrence of tumors. The study observed no recurrence of metastatic disease within the observational period, suggesting that metastasis had been eliminated.

The choice of microRNA-10b as a target is supported by its potentially broad relevance to cancer. Recent studies have demonstrated that the influence of microRNA-10b extends beyond breast cancer to 17 other tumor types including pancreatic, lung,

colorectal, gastric, bladder, ovarian, and hepatocellular cancer amongst others, suggesting that the described approach may be broadly applicable to metastatic disease. In addition, TTX-MC138's mechanism of action is hormone receptor independent, and has been observed to treat metastatic breast cancer in rodents regardless of hormone receptor type (ER+/-, PR+/-, HER2+/-, or combinations thereof).

Our understanding of the miR-10b pathway and its effects is constantly evolving. However, the downstream effects of miR-10b as we currently understand them include promotion of migration and invasion, promotion of epithelial-mesenchymal transition (EMT), inhibition of apoptosis, promotion of proliferation, induction of angiogenesis, self-renewal and effects on immune modulation.

Known microRNA-10b targets include Homeobox D10, or HOXD10, implicated in tumor cell migration and invasion, c-JUN, a critical inducer of cell proliferation and tumor progression, and phosphatase and tensin homolog (PTEN), which results in maintained AKT activation, a Ser/Thr kinase associated with proliferation, apoptosis, and growth. This effect on the AKT pathway allows for the improved self-renewal found in cancer stem cells highly expressing miR-10b. The key pathways through which miR-10b exerts its pro-metastatic effects are summarized in **Fig. 3**.

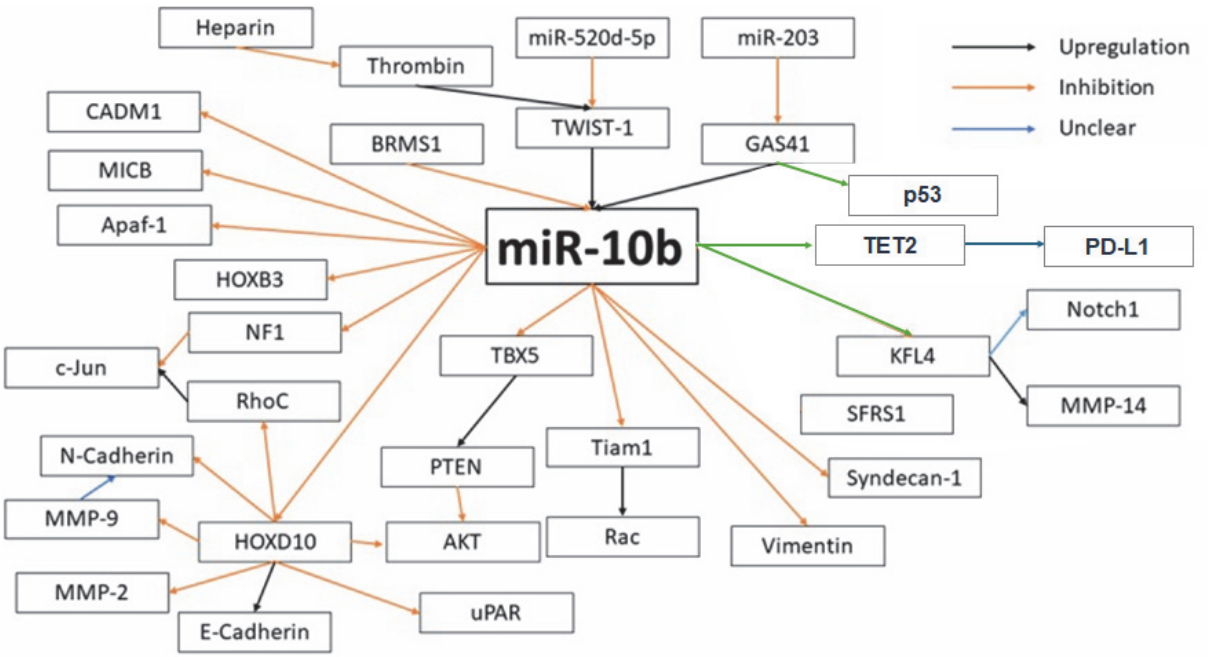

Figure 3. *Key signaling pathways influenced by miR-10b.*

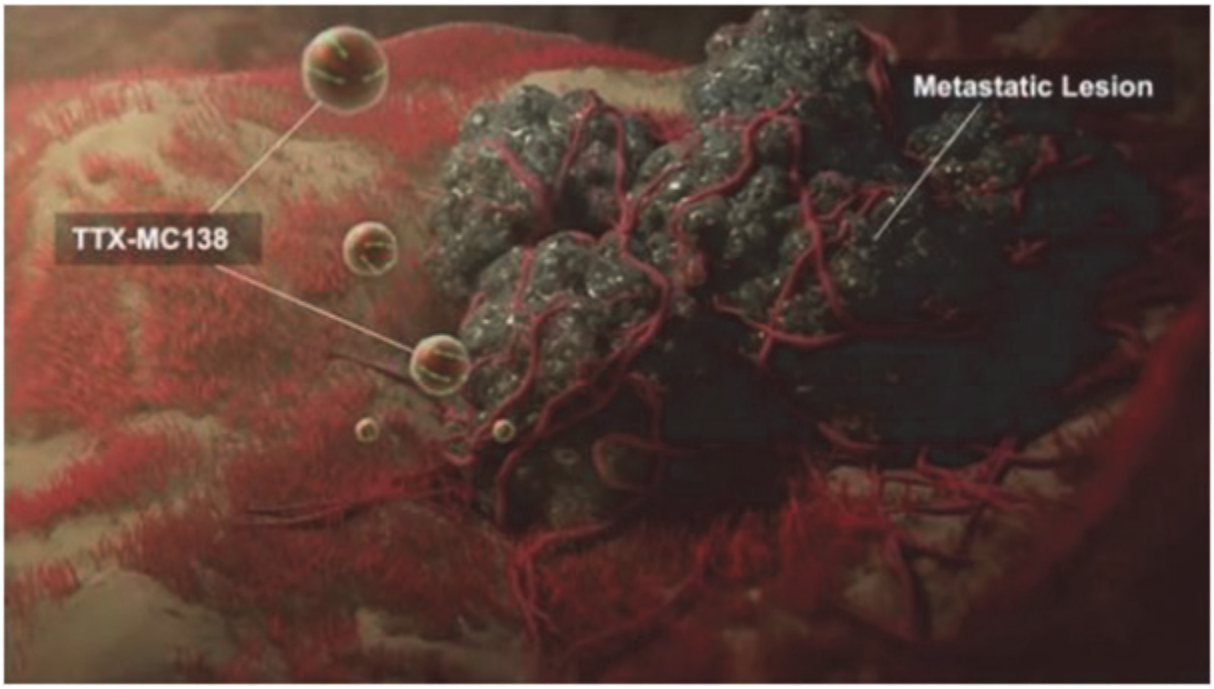

Figure 4. *Depicts TTX-MC138 delivery to metastatic lesions, infiltrating tumor cells to engage and inhibit miR-10b, designed to lead to tumor cell death.*

Mechanism of Action of TTX-MC138

Our therapeutic concept is summarized in **Fig. 4**. TTX-MC138 represents a proprietary therapeutic candidate that inhibits microRNA-10b. In primary tumors, inhibition of microRNA-10b by TTX-MC138 leads to arrest of tumor cell dissemination to local and distant organs. We believe a combination of TTX-MC138 with low-dose doxorubicin may lead to metastatic cell death and complete and persistent regression of already formed metastatic lesions in local and distant organs. Low-dose doxorubicin was used to slow down cell division in tumor cells. In preclinical studies that utilize aggressive metastatic tumor models, the use of low dose doxorubicin was necessary to allow TTX-MC138 to fully inhibit microRNA-10b. Because metastatic growth is slower in humans, the use of a cytostatic such as doxorubicin will likely be unnecessary.

Results

In our preclinical studies outlined in **Fig. 5**, when TTX-MC138 was combined with a low-dose cytostatic (doxorubicin), there was complete and persistent regression of pre-existing metastatic cancer with no evidence of recurrence and no systemic toxicity. In preclinical studies that utilized aggressive metastatic tumor models, doxorubicin was used to allow TTX-MC138 to fully inhibit microRNA-10b. Because metastatic cell growth is slower in humans, we do not believe that a cytostatic such as doxorubicin will be necessary.

Specifically, in a model of stage II/III breast cancer in mice with lymph node metastases, just four weekly treatments eliminated metastatic burden. By contrast, in the control groups, there was metastatic progression (Within-Subjects ANOVA: $p < 0.05$). Once metastases were eliminated, therapy was stopped. Thereafter, the animals were observed by bioluminescence optical imaging to detect

recurrence. No recurrence of metastatic disease was observed by the end of the study at 12 weeks after tumor implantation. This translated into 100% survival.

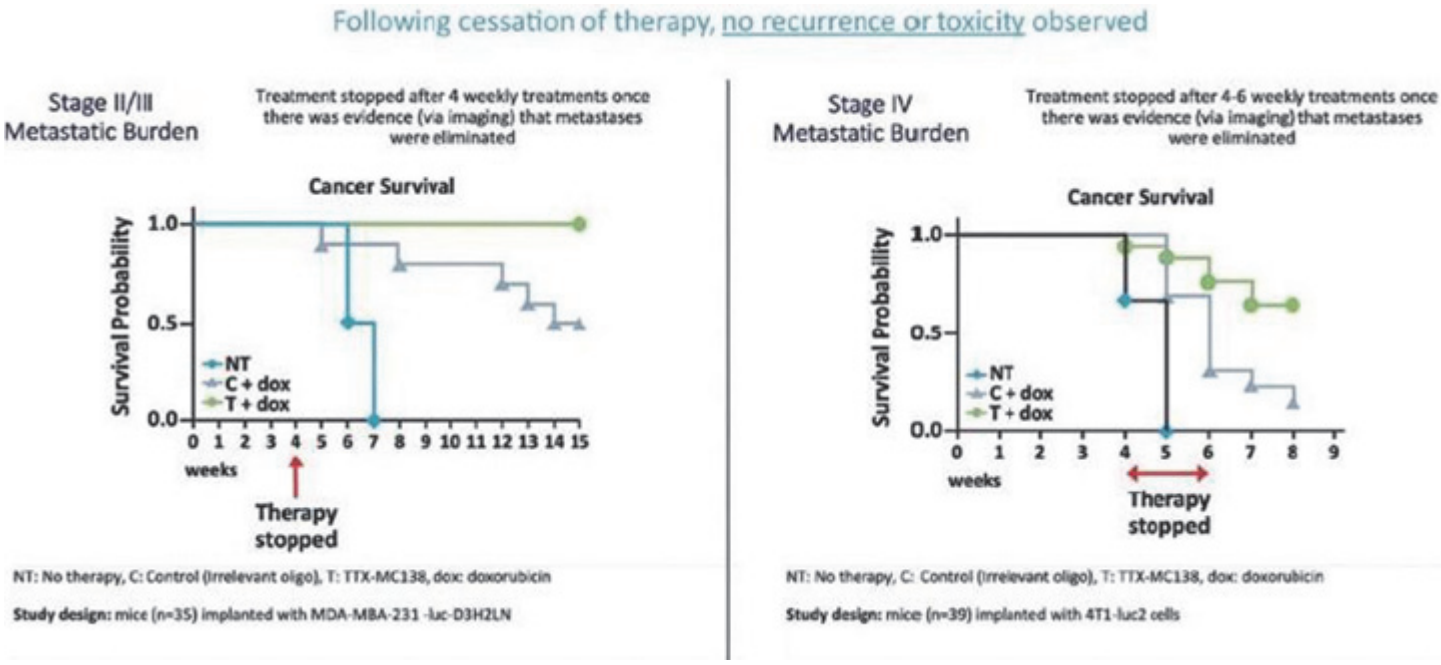

Figure 5. *Preclinical activity of TTX-MC138 in models of metastatic breast cancer.*

In a model of stage IV breast cancer in mice, we obtained 65% survival. Specifically, in 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: $p < 0.05$).

We found no elevation in serum biochemistry markers following treatment suggesting the absence of acute toxicity associated with the therapeutic candidate. In addition, histopathology of major organs resulted in no observed gross tissue abnormalities suggesting that there was no toxicity as a result of treatment.

Positive Preclinical Results with TTX-MC138 in Pancreatic Adenocarcinoma

We have evaluated the efficacy of TTX-MC138 applied as monotherapy in a murine model of pancreatic adenocarcinoma. In this study, we treated mice bearing human pancreatic tumors implanted in their pancreata with TTX-MC138 once weekly for eight weeks. The candidate demonstrated a pharmacodynamic response by successfully inhibiting its target, 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. Animals treated with TTX-MC138 showed an approximate 50% reduction of metastases compared to animals treated with gemcitabine.

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.

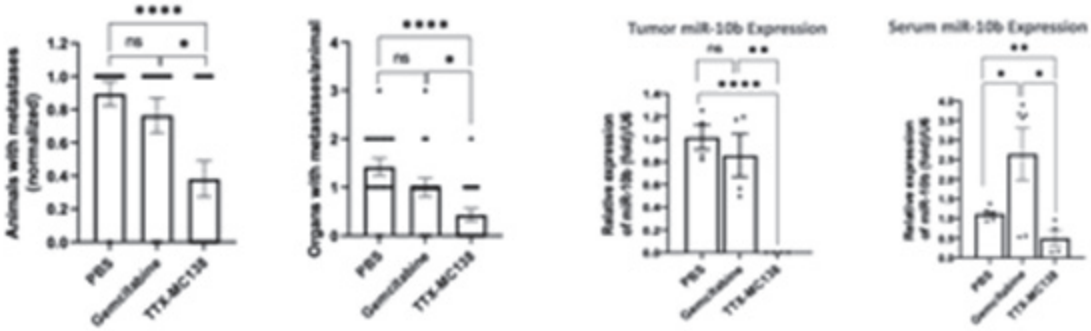

Figure 6. *We have evaluated the efficacy of our lead therapeutic candidate, TTX-MC138, applied as monotherapy in a murine model of pancreatic adenocarcinoma. In this study, we treated mice bearing orthotopic xenografts derived from human pancreatic adenocarcinoma cells with TTX-MC138 once weekly for eight weeks. Animals treated with phosphate buffered saline or gemcitabine served as controls. Metastasis was significantly inhibited in animals treated with TTX-MC138 versus controls. The number of animals with evidence of metastasis and the number of metastasis-bearing organs per animal were reduced by approximately 50% in animals treated with TTX-MC138 versus gemcitabine. Importantly, TTX-MC138 demonstrated a pharmacodynamic response by successfully inhibiting its target, microRNA-10b (miR-10b).*

TTX-MC138 Clinical Development

Phase 0 — First-in-Human Clinical Study

We conducted our FIH Phase 0 clinical trial at MGH, a major cancer center, in August 2023. The primary purpose of this trial was to demonstrate clinical delivery of TTX-MC138 to metastatic tumor lesions. Another objective of the Phase 0 trial was to evaluate the pharmacokinetics of a radiolabeled version of our therapeutic candidate. While only one patient was treated in this trial, this patient had metastatic lesions in three locations – bone, lungs and liver – and we obtained the results we expected. Namely, the data from this patient showed that radioactivity consistent with accumulation of TTX-MC138 was detected by noninvasive imaging in the regions of the metastatic lesions previously identified by fluorodeoxyglucose /positron emission tomography. In addition, radiolabeled TTX-MC138 had pharmacokinetic behavior consistent with that expected based on non-clinical IND-enabling studies. The patient tolerated the dosing with no reported adverse reactions. Metabolite analysis indicated circulation of intact radiolabeled TTX-MC138 for more than 20 hours, equivalent to that predicted by Drug Metabolism and Pharmacokinetics (DMPK) modelling, and that the drug candidate analyzed in the blood was identical to that of the manufactured drug candidate, demonstrating *in vivo* stability. Complete analysis of data from this first patient will be included in the final clinical study report for the study.

The Phase 0 clinical trial offered the potential to:

- demonstrate quantifiable evidence of delivery of TTX-MC138 to metastatic lesions in subjects with advanced solid tumors;
- inform Phase I/II clinical trials by measuring pharmacokinetics and biodistribution in some vital organs and other tissues;
- inform therapeutic dose levels based on microdose results; and
- validate delivery for the TTX pipeline more broadly, potentially opening-up additional relevant RNA targets that have been previously undruggable due to challenges with RNA delivery.

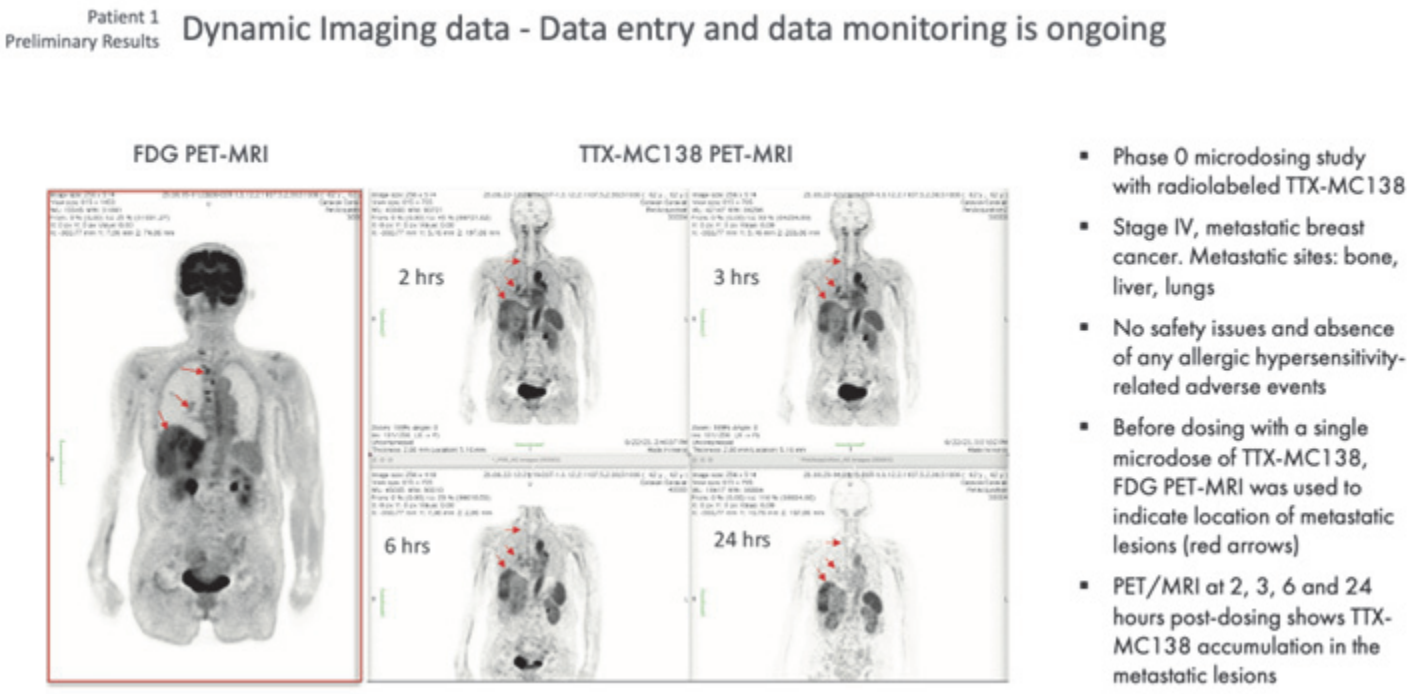

Figure 7. Evidence of accumulation of radiolabeled TTX-MC138 in clinical metastases.

Phase I/II Clinical Trial

In April 2024, we received an Investigational New Drug "Study May Proceed" letter from the FDA to conduct a Phase I/II clinical trial.

Trial Description

The Phase 1a dose escalation and expansion clinical trial, is an open-label, multicenter study in cancer patients with advanced solid tumors designed to assess the safety of the therapeutic candidate in humans, including observing potential side effects, and to determine the maximum tolerated dose, or MTD, of TTX-MC138 for treating subjects with metastatic cancer. It is anticipated that study subjects will have had prior surgical resection of their primary tumors.

Trial Objectives

- To evaluate the safety and tolerability of escalating dose levels of TTX-MC138 to determine the MTD from which we anticipate selecting a recommended Phase 2 dose.
- To evaluate the anti-tumor activity of TTX-MC138 in subjects with advanced solid tumors.
- To evaluate anti-tumor activity of escalating dose levels of TTX-MC138.
- To evaluate immunogenicity of TTX-MC138.
- To characterize the pharmacokinetics (PK) profile of TTX-MC138.
- To explore the pharmacodynamic (PD) effect of TTX-MC138 on biomarker expression, which may include miR-10b expression, Ki-67 tumor cell proliferation, and downstream miR-10b targets.

This study is designed to be a dose escalation and expansion study in which a Bayesian Optimal Interval, or BOIN, Design will be employed to inform dose-escalation among cohorts in the dose escalation phase of the study.

Trial Progress

On September 17, 2024, we announced the dosing of the first subject in the Phase I/II clinical trial.

On October 10, 2024, we announced completion of the initial dosing of the first cohort of three patients in the Phase I/II clinical trial.

On October 23, 2024, we announced the clinical trial's Safety Review Committee's authorization to proceed with dosing the second patient cohort.

On January 14, 2025, we announced that we had dosed the first patient in the third cohort of our phase I/II clinical trial.

On March 13, 2025, we announced the Safety Review Committee's authorization to proceed with dosing the fourth patient cohort.

On March 27, 2025, we announced that we had dosed the first patient in the fourth cohort of our phase I/II clinical trial.

On May 8, 2025, we announced that three patients had been treated in the fourth cohort.

On October 14, 2025, we announced completion of the Phase 1a portion of the trial, that the trial met the primary endpoint of safety, and the decision to move forward into the next stage of clinical evaluation to assess the efficacy of TTX-MC138 across selected metastatic diseases.

TTX-siPDL1

Pancreatic cancer is the fourth-leading cause of cancer-related death in the United States with an overall 5-year survival rate of only 8%. Surgical resection remains the treatment of choice for patients with resectable disease. However, less than 20% of the diagnosed patients qualify for curative resections, 30% of patients present with regional disease, and 50% present with distal metastases with survival rates of 11% and 2%, respectively. The reasons behind such poor prognosis have been postulated to involve the advanced stage at the time of diagnosis, and resistance to standard chemotherapies. However, these therapies are heavily dependent on the patient's overall health, and the overall survival benefit for the latest cytotoxic combination therapies is only approximately two to five months.

Considering the tremendous suffering caused by this disease and the modest progress achieved thus far with cytotoxic treatments, we believe there is a need to explore radical, transformative approaches for therapy that attack the disease from multiple angles. The last decade has seen tremendous progress in the field of cancer immunotherapy. In fact, immunotherapy represents the most promising new cancer treatment approach since the development of the first chemotherapies in the 1940s. Checkpoint inhibitors have worked against lethal cancers such as melanoma and some lung cancers — sometimes with dramatic success — and are being tested in dozens of other cancer types. However, pancreatic cancer has proven difficult to treat with conventional drugs and has been resistant to initial immunotherapy approaches. Partly, the reason for this is the tumor microenvironment that characterizes pancreatic adenocarcinoma, which is both immunosuppressive in nature and a physical barrier for antibody and T lymphocyte infiltration. Consequently, it is important to design alternative approaches that combine innovative checkpoint inhibitors that can be delivered efficiently to tumor cells and tumor resident macrophages, and strategies that enhance the permeation of the tumor by T lymphocytes.

In our initial preclinical study, we administered combination therapy consisting of gemcitabine and TTX- siPDL1 in a syngeneic murine pancreatic cancer model over a seven-week treatment period. Our study investigators observed significantly lower morbidity and toxicity, tumor regression and a dramatic improvement in survival. In particular, following dose optimization, a 90% reduction in tumor volume was observed after two weeks of treatment. Within the study, 100% of the control animals (i.e., those treated with an inactive version of TTX-siPDL1, named TTX-siSCR, in place of TTX-siPDL1) had succumbed to their tumors within six weeks after the beginning of treatment, while none of the experimental animals treated with a high dose of the active therapeutic candidate, TTX-siPDL1, had succumbed at week six of treatment, and 67% of these animals survived for 12 weeks.

Our pancreatic cancer studies illustrated the potential of a combination treatment with gemcitabine and TTX-siPDL1. Study mice co-treated with TTX-siPDL1 and gemcitabine showed significant inhibition of tumor growth relative to controls ($p < 0.05$). This difference was evident two weeks after beginning treatment **(Fig. 8A)**.

The presumed advantage of the combination treatment was demonstrated in the study when assessing animal survival **(Fig. 8B)**. In the study, 67% of the mice treated with gemcitabine and TTX-siPDL1 (high dose) survived for 12 weeks while 67% of the mice treated with gemcitabine and TTX-siPDL1 (low dose) survived until week eight. All of the control mice treated with TTX-siSCR and gemcitabine succumbed by week six. Within the study, all of the mice in the group treated with gemcitabine and TTX-siSCR developed large necrotic tumors, presumably due to the high rate of tumor growth. Tumor necrosis and ulceration were not seen in the animals treated with the combination therapeutic candidate.

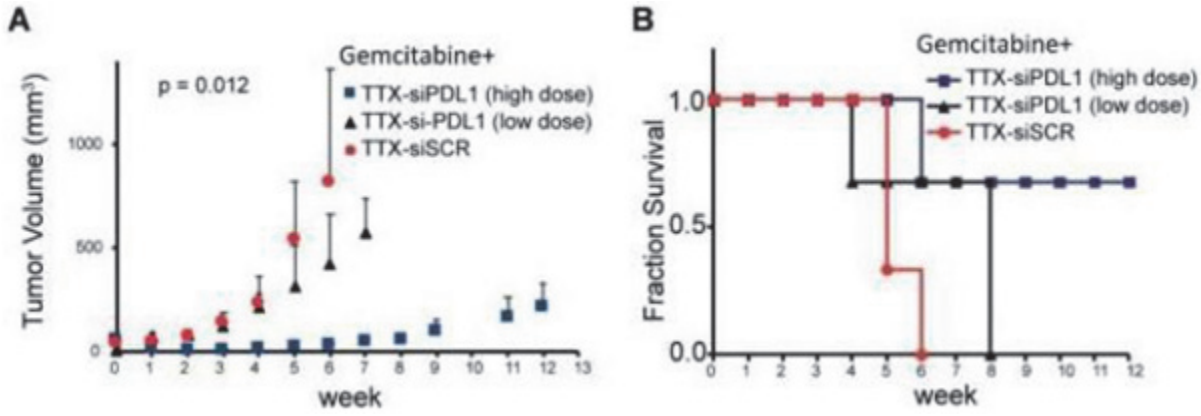

Figure 8. *Outcome of treatment with TTX-siPDL1 and gemcitabine, or Gem. The mice were treated with Gem (333.3 mg/kg) in solution with a low dose of either TTX-siPDL1 or siSCR (10mg/kg Fe; 520 nmoles/kg siRNA in both groups) or a high dose of TTX-siPDL1 or siSCR (10 mg/kg Fe, 937 nmoles/kg siRNA in both groups).*

Our preclinical data were used in support of our application for Orphan Drug Designation which we received in June 2022. More recently, we carried out studies in a highly aggressive syngeneic orthotopic animal model of pancreatic ductal adenocarcinoma, or PDAC, that is characterized by intense desmoplasia, similar to human PDAC. Specifically, in this model, in untreated animals, tumor volume grew 788-fold over the course of 5 weeks, with 30-40% of the tumor mass attributed to a fibrous capsule. We implanted Hy15549 cells into the pancreas of C57BL/6 mice. Once tumors measured over 2 mm in diameter, as measured by anatomic MRI, treatment was initiated and involved gemcitabine (6.66 mg/mouse) and TTX-siPDL1 at two doses: low dose (1500 nmoles siRNA/kg) or high dose (2000 nmoles siRNA/kg). Our studies demonstrated that TTX-siPDL1 was successfully delivered and effective even in the highly desmoplastic and hypovascular Hy15549 murine model of PDAC, which has been deemed nonresponsive to antibody-based immune checkpoint blockade. Anatomic MRI showed that in the animals treated with high-dose TTX-siPDL1 alone or in combination with gemcitabine, tumor growth rates were lower than in the PBS controls (**Fig. 8**).

After two weekly treatments with TTX-siPDL1 plus gemcitabine, tumor volumes were four times smaller than in untreated animals. Importantly, animal survival was improved dramatically in animals treated with TTX-siPDL1 plus gemcitabine compared to all other groups. Among the animals treated with TTX-siPDL1 plus gemcitabine, the hazard ratio for overall survival (OS) relative to PBS was 0.08. Interestingly, even in the absence of gemcitabine, TTX-siPDL1 as monotherapy improved survival more dramatically than gemcitabine (HR, 0.24 for TTX-siPDL1 vs. 0.42 for gemcitabine) (**Fig. 9**). Immunohistology on the tumor tissues post-necropsy indicated that the treatment inhibited PD-L1, increased CD8+T cell recruitment, reduced Treg abundance, and increased immune cell toxicity as measured by Granzyme B levels. These findings were accompanied by lower cell proliferation, as shown by Ki-67 staining. Finally, as an initial measurement of tissue damage due to the treatment, we analyzed major organs by histopathology and saw no differences from the vehicle-treated controls. Considering the aggressive and fibrous nature of the Hy15549 model and its resistance to traditional checkpoint inhibitors, the described RNAi-based therapeutic approach could be promising against PDAC and could make an impact on one of the most intractable cancers which has long evaded the power of modern medicine to deliver long-term survival.

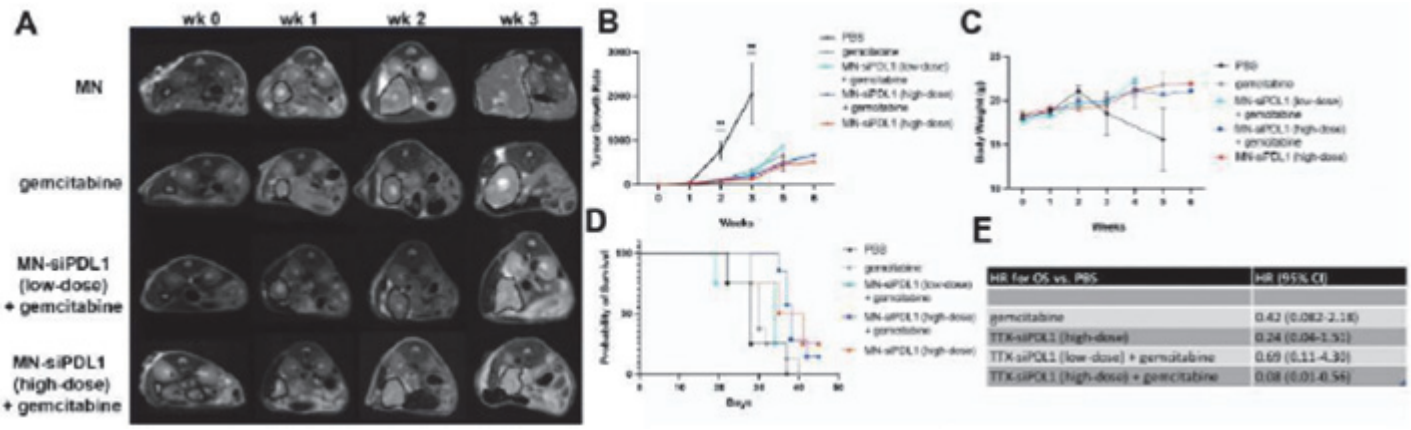

Figure 9. *Combination treatment with gemcitabine and TTX-siPDL1 (depicted in Figure as MN-siPDL1). Image on left: Representative T2- weighted MR images during the course of treatment. Tumors were segmented manually using ImageJ. Graph in middle, top: Change in tumor volume during treatment Graph on right, top: Change in body weight during treatment. Graph in middle, bottom: Kaplan-Meier survival analysis demonstrating survival improvement in animals treated with high-dose TTX-siPDL1 plus gemcitabine vs. control groups. Table on right, bottom: Hazard Ratios for Overall Survival.*

TTX-RIGA

Immunotherapies represent powerful alternatives to traditional clinical treatments for cancer. Recent developments in the use of Pattern Recognition Receptors, or PRRs, specifically retinoic acid-inducible gene I-like receptors, aim to harness the innate power of the immune system for anti-cancer therapy. Retinoic acid-inducible gene I, or RIG-I, is a cytosolic nucleic acid sensing Pattern Recognition Receptor of the innate immune system. It is essential for recognizing certain RNA viruses. RIG-I is ubiquitously expressed in all cell types including tumor cells. RIG-I engagement leads to tumor cell death, and to activation of the innate and adaptive immune systems. These factors suggest it could be an attractive therapeutic approach in oncology.

Our therapeutic candidate, TTX-RIGA, is in preclinical development. TTX-RIGA is designed to utilize our proprietary delivery system to deliver a RIG-I agonist to tumor cells. TTX-RIGA is intended to activate the RIG-I signaling pathway, in turn triggering an immune response that targets cancer. The results of the testing we have completed support continuation of our research with this candidate. A manuscript detailing feasibility studies with RIGA was recently published in BioRxiv. Furthermore, we have demonstrated successful synthesis of TTX-RIGA and its capability to agonize RIG-I and induce immune activation. In an animal model of melanoma, treatment with TTX-RIGA injected intravenously over six consecutive days inhibited tumor growth and, importantly, largely arrested the growth of secondary recurrent tumors implanted six days after the final treatment due to activation of a type I IFN immune response. This effect was not seen in animals injected intratumorally with a current standard-of-care RIG-I agonist (**Fig. 10**).

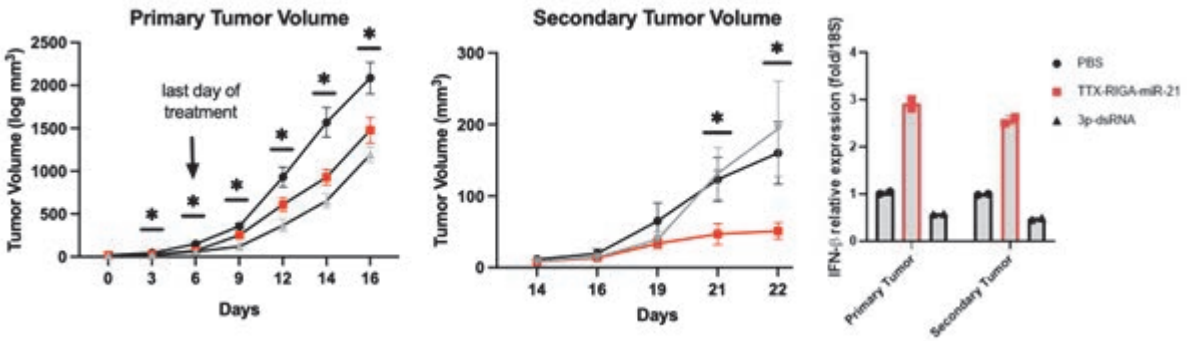

Figure 10. *C57BL/6 mice were implanted subcutaneously with B16-F10 cells. Treatment was initiated once tumors were established. Treatment continued until day 6 after tumor implantation. On day 12 after the beginning of treatment, a secondary tumor challenge with the same cell line was performed by subcutaneous implantation into the contralateral flank.*

TTX-siMYC

TTX-siMYC is a siRNA-based inhibitor of c-MYC, a widely expressed but currently undruggable oncogene. The c-MYC proto-oncogene is one of the most frequently activated oncogenes and is estimated to be involved in 20% of all human cancers. C-MYC codes for a transcription factor that regulates the expression of multiple genes responsible for cell growth and proliferation, differentiation, programmed cell death, and metabolism.

In cancer, c-MYC is often constitutively expressed. For example, a common human translocation involving c-CYC is critical to the development of most cases of Burkitt lymphoma. In addition, c-MYC has also been implicated in carcinoma of the cervix, colon, breast, lung and stomach.

MYC is viewed as a promising target for anti-cancer drugs. However, it has proven difficult to drug to date at the protein level. This may present an opportunity for us to target the gene at the RNA level.

Seviprotimut-L

Seviprotimut-L is an allogeneic, polyvalent, partially purified shed melanoma antigen vaccine derived from three proprietary human melanoma cell lines: SFHM2, SFHM4 and SFHM8 and bound to alum as an adjuvant. Seviprotimut-L stimulates humoral and cellular immune responses. Melanoma-associated antigens (MAAs) found in seviprotimut-L are taken up by antigen-presenting cells (e.g., dendritic cells) which then activate the production of antigen-specific cytotoxic T-lymphocytes (CTLs) as well as develop antibody responses against MAAs. These CTLs and antibodies then recognize and act on tumor cells expressing the MAAs on their surfaces, causing cell death. Seviprotimut-L is currently in development for the adjuvant treatment of patients with Stages IIB and IIC melanoma, following definitive resection.

Seviprotimut-L received an FDA Fast track designation in 2020 and a Special Protocol Assessment (SPA) to run the pivotal Phase 3 Melanoma Antigen Vaccine Immunotherapy Study (MAVIS) trial in 2022 for stage IIB/IIC melanoma. The final analysis of Part B1 data from the MAVIS trial demonstrated that a subgroup analysis of patients receiving seviprotimut-L with AJCC Stage IIB/IIC melanoma, under age 60 with a median follow-up time of 45.8 months (3.8 years), showed clinically significant improvement in recurrence-free survival (RFS), reducing the risk of disease recurrence or death by 68% (HR=0.32; 95% CI, 0.121, 0.864) compared to patients receiving placebo. Additionally, RFS was more favorable in patients under age 60 with ulcerated melanomas (HR 0.21; 95% CI: 0.065-0.702), and there was a trend toward improved overall survival (OS) (HR 0.34; 95% CI: 0.117, 0.975) for patients that received seviprotimut-L compared to those receiving placebo. Seviprotimut-L was extremely well tolerated, with adverse events (AEs) similar to patients that received placebo; there were no immune-mediated AEs or other treatment-related serious AEs observed.

Unleash Program

In March 2026, TransCode announced that it obtained the rights to license and develop three pre-clinical stage drug candidates, UIO 524, UIO 525 and UIO 526 from Unleash. The addition of UIO-524 complements and expands TransCode's oncology pipeline by introducing a next-generation, biology-driven oncolytic immunotherapy platform designed to address solid tumor indications with high-unmet medical need, beginning with muscle-invasive bladder cancer (MIBC).

UIO-524 is a next generation, rationally-designed oncolytic adenovirus engineered to selectively replicate within both malignant cells and cancer-associated stroma. The virus delivers a multi-cytokine immune-activating payload comprising CD40-L, 4-1BBL, and IL-21, intended to activate dendritic cells, T cells, and NK cells and to drive a robust, systemic anti-tumor immune response. The hybrid SPARC promoter drives stromal-tumor-specific virus replication.

Accelerated Regulatory Programs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs addressing unmet medical needs or for treating serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval. The purpose of these programs is to expedite either the development or the review of certain new drugs to get them to patients sooner than under standard FDA development and review procedures. We anticipate seeking one or more of these qualifications, but there is no assurance that we will obtain any of them.

Orphan Drug Designation

The Orphan Drug Act was enacted by the 97th Congress in 1983 to facilitate the development of drugs that impact smaller patient populations. Benefits available under the Orphan Drug Act include seven-year marketing exclusivity, 25% tax benefits for research & development activities performed in the U.S., a waiver of Prescription Drug User Fee Act, or PDUFA, Fees, and qualification to compete for research grants.

Based on *in vivo* studies using TTX-siPDL1 to treat human pancreatic tumors implanted in animals, we applied for and, in June 2022, received, Orphan Drug Designation for the treatment of pancreatic cancer. In addition, in February 2023, we received Orphan Drug Designation from the FDA for TTX-MC138, also for the treatment of pancreatic cancer. We intend to conduct additional *in vivo* studies to support filings of other TTX-based drug candidates in other orphan disease indications including osteosarcoma and small cell lung cancer, or SCLC. In the Michigan State University laboratory of one of our scientific co-founders, animal testing of TTX-MC138 in glioblastoma cells has been completed. Mechanistic studies have produced efficacy signals in combination with temozolomide, or TMZ, in glioblastoma multiforme, or GBM, cell lines. A manuscript summarizing results from this study has been submitted for publication.

There is no assurance that we will obtain any additional Orphan Drug Designations.

INTELLECTUAL PROPERTY

Our intellectual property, or IP, portfolio is directed to our therapeutic candidates and their targeted use and development in specific patient populations and in specific indications. Comprised primarily of intellectual asset types of patents, trademarks, know-how and trade secrets, our rights-based portfolio currently consists of seven different patent families and one trademark. Our patent portfolio comprises issued patents, pending patent applications and new provisional patent applications. We have licensed rights to patents issued in the U.S. which we believe provides exclusivity for a significant portion of the potential worldwide market for TTX-MC138, our lead candidate, and are pursuing additional filings in both the U.S. and elsewhere. Patents we have licensed for a TTX-MC138-associated biomarker test have issued in both the U.S and in the European Union. Seviprotimut-L is based on proprietary cell lines. UIO-524, 525, and 526 are protected by an issued patent and two Patent Cooperation Treaty, or PCT, applications in the U.S. and Europe.

Trademarks

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. On October 20, 2021, TransCode Therapeutics, Inc. applied to the United States Commissioner of Trademarks to register 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.

Therapeutic Patent Rights Assigned to TransCode

Template Directed Immunomodulation for Cancer Therapy

- International Application (PCT/US2021/65580) filed December 30, 2021. Corresponding national stage applications are pending in the United States, Canada, Japan, Australia, Europe and Korea.

Nanoparticle and Template Directed Rig-I Agonist Precursor Compositions and Uses thereof for Cancer Therapy

- International Application (PCT/US/2023/026460) filed June 28, 2023. Corresponding national stage applications are pending in the United States, Europe, and Japan.

Pharmaceutical Formulations, Dosing and Methods for the Treatment of Advanced Solid Tumors

- U.S. Provisional Application No. US 63/898.419 filed October 13, 2025.

Methods for the Treatment of Minimal Residual Disease of Colorectal Cancer (CRC)

- U.S. Provisional Application No. 63/963,986 filed January 20, 2026

Unleash (UIO) acquired Patents

Isolated DNA fragment of the SPARC human promoter and its use for driving the expression of an heterologous gene in tumor cells

- U.S. Patent No. 8.346.160: granted May 7, 2013

Oncolytic Adenoviral Vector and Methods of Use

- International PCT Application No. PCT/US2020/019179 filed February 21, 2020. Corresponding national stage U.S. application granted as U.S. Patent No. 11,542,526.

Oncolytic Adenoviral Vector and Methods of Use

- International PCT Application No. PCT/US2023/074623 filed September 20, 2023. Corresponding national stage applications are pending in the United States and Europe.

Therapeutic Patent Rights (Covered under MGH License)

Therapeutic Nanoparticles and Methods of Use Thereof

- US 9,763,891 — Granted (Issued September 2017). Expiry not expected before 2032.
- US 9,629,812 — Granted (Issued April 2017). Expiry not expected before 2032.
- US 10,463,627 — Granted (Issued November 2019). Expiry not expected before 2032.

Biomarker Patent Rights (Diagnostic test) miRNA Profiling Compositions and Methods of Use

- US 10,086,093 — Granted (Issued October 2018). Expiry not expected before 2034.
- US 18/339,621 — Pending.
- EP 2961386 — Granted (Issued July 2019). Expiry not expected before 2034.

Compositions and Methods for Tunable Magnetic Nanoparticles

- PCT/US 2020/63635 — Application filed December 7, 2020. Corresponding national stage applications pending in Australia, Canada, China, Europe, Hong Kong, Japan, Korea, and the U.S. Expiry not expected before 2040.

Compositions and Methods for Immune Checkpoint Inhibition

- PCT/US 2019/050003 — Application filed September 6, 2019. Corresponding national stage filings pending in Australia, Canada, China, Europe, Japan, Korea, and the U.S. Expiry not expected before 2038.

MGH LICENSE

In November 2018, we entered into a license agreement with MGH, or the MGH License, pursuant to which MGH granted us an exclusive, world-wide, royalty-bearing, sub-licensable license to certain MGH intellectual property which we collectively refer to as the Licensed Patents.

We are required to pay tiered royalties of a low to middle single-digit percentage on annual net sales of products related to the Licensed Patents. Initially, there were minimum royalties of $25,000 per year prior to the first commercial sale of a product or process covered by the Licensed Patents, and a minimum of $50,000 per year after the first commercial sale of a product or process covered by the Licensed Patent.

Upon the occurrence of certain milestones, we are also obligated to make payments of up to an additional $1.55 million in aggregate. As of the date of this annual report, no milestone events had been achieved.

Unless earlier terminated, the MGH License will expire upon the latest of (i) the date on which all issued patents and filed patent applications subject to the License have expired or been abandoned; (ii) expiration of the last to expire regulatory exclusivity covering a covered product or process; or (iii) 10 years after the first commercial sale of a product or process covered by the Licensed Patents.

In the event of a default in our performance of the MGH License that we fail to cure, MGH may terminate the MGH License with respect to the country or countries in which the default occurs. MGH may terminate the MGH License immediately upon written notice to us in the event of our bankruptcy, insolvency, dissolution or winding up, or if we fail to maintain the insurance required pursuant to the MGH License. MGH may also terminate the MGH License upon written notice if we fail to make payments due under the MGH License. We may terminate the MGH License at any time by providing ninety (90) days written notice to MGH. Any sublicenses granted by us under the MGH License shall be automatically terminated upon the termination of the MGH License, but MGH is required to make a good faith effort to enter into a direct license agreement with any sublicensee who so requests.

Amendments to MGH License Agreement

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

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

Upon expiration of the MGH License, the licenses granted to us pursuant thereto will be considered fully paid and royalty-free.

Effective August 15, 2025, we and MGH amended the MGH License again. Under the second amendment the timelines for the pre-sales requirements for Patent Family 1 (as defined in the MGH License) were updated, and the requirements and timelines for the pre-sales requirements for Patent Family 2 (as defined in the MGH License) were updated. In addition, the aggregate dollar amount of one-time milestone payments we are obligated to pay MGH upon certain milestones was increased from $1,550,000 to $2,950,000 for each patent family; and the individual amounts for therapeutic product- or processes-related milestone payments were updated.

UNLEASH LICENSE

In March 2026, we entered into the Unleash Licensing Agreement pursuant to which we acquired a pre-clinical candidate program involving genetically-engineered adenoviruses to harness the immune system to fight cancer, as well as an exclusive, perpetual, irrevocable, worldwide, fully-paid up, royalty-free, sublicensable right and license to related technology. As consideration for the Unleash Licensing Agreement, pursuant to the Unleash Registration Rights Agreement, we agreed to issue 1,136,364 shares of

our Series C Preferred Stock to Unleash. The Series C Preferred Stock is not convertible until our stockholders approve its conversion into Common Stock in accordance with the listing rules of Nasdaq. Following the Unleash Stockholder Approval, each share of Series C Preferred Stock is convertible into one share of our Common Stock.

COMPETITION

The pharmaceutical industry is intensely competitive and constantly evolving. While we believe that our experience, scientific knowledge and intellectual property provide us with certain competitive advantages, these may not be sufficient to succeed. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies. Most of our potential competitors are larger than we are, and they have substantially greater capital and human resources than we do. Many also have established market positions and expertise and capabilities in sales, marketing, distribution, clinical trials and regulatory matters. Not only must we compete with other companies that are focused on RNA therapeutics and other therapeutics that treat cancer, but also any therapeutic candidates that we successfully develop and commercialize must compete with existing therapies and new therapies that may become available in the future. In addition, we compete with other life sciences companies generally for employees, consultants and advisors, supplies and materials, and laboratory facilities and equipment.

Our competitors may develop more successful products that are similar to ours, but sooner than we can commercialize ours, which may negatively impact our results.

There are several companies operating in the “targeted therapy” space, many of which have existed longer than we have, with the advantages described above. The development of targeted therapies requires the identification of good targets — that is, targets that play a key role in cancer cell growth and survival. (It is for this reason that targeted therapies are sometimes referred to as the product of “rational” drug design.)

One approach to identify potential targets is to compare individual proteins in cancer cells with those in normal cells. Proteins that are present in cancer cells but not normal cells, or that are more abundant in cancer cells, could be potential targets, especially if they are known to be involved in cell growth or survival. An example of such a differentially expressed target is the human epidermal growth factor receptor 2 protein, or HER-2. HER-2 is expressed at high levels on the surface of some cancer cells. Several targeted therapies are directed against HER-2, including trastuzumab (Herceptin), which is approved to treat certain breast and stomach cancers that overexpress HER-2.

Another approach to identify potential targets is to determine whether cancer cells produce mutant (altered) proteins that drive cancer progression. For example, the cell growth signaling protein BRAF is present in an altered form (known as BRAF V600E) in many melanomas. Vemurafenib (Zelboraf) targets this mutant form of the BRAF protein and is approved to treat patients with inoperable or metastatic melanoma that contains this altered BRAF protein.

Researchers also look for abnormalities in chromosomes that are present in cancer cells but not in normal cells. Sometimes these chromosome abnormalities result in the creation of a fusion gene (a gene that incorporates parts of two different genes) whose product, called a fusion protein, may drive cancer development. Such fusion proteins are potential targets for targeted cancer therapies. For example, imatinib mesylate (Gleevec) targets the BCR-ABL fusion protein, which is made from pieces of two genes that join together in some leukemia cells and promotes their growth.

There are a number of oncology companies with targeted therapeutics for various cancers with therapeutic candidates in various stages of preclinical and clinical development. Companies focusing on RNA therapeutics for oncology include Arrowhead Pharmaceuticals, Ionis, Moderna, Alnylam, BioNTech, Dicerna, and Siranomics, among others. We believe these companies lack delivery systems that are able to target genes inside tumors and metastases. We know of no other RNA companies currently in clinical development that have an exclusive focus on cancer and whose pipelines are not limited to a single RNA technology such as siRNA or mRNA vaccines. By contrast, TransCode’s pipeline spans a spectrum of RNA technologies and includes ncRNAs, RNA vaccines, and immunostimulatory RNAs solely for oncology.

Targeted therapy

Targeted cancer therapies are drugs or other substances that block the growth and spread of cancer by interfering with specific molecules ("molecular targets") that are involved in the growth, progression, and spread of cancer. Targeted cancer therapies are sometimes called "molecularly targeted drugs," "molecularly targeted therapies," "precision medicines," or similar names.

Targeted therapies differ from standard chemotherapy in several ways:

- Targeted therapies act on specific molecular targets that are associated with cancer, whereas most standard chemotherapies act on all rapidly dividing normal and cancerous cells.

- Targeted therapies are deliberately chosen or designed to interact with their target, whereas many standard chemotherapies were identified because they kill cells.

- Targeted therapies are often cytostatic (that is, they block tumor cell proliferation), whereas standard chemotherapy agents are cytotoxic (that is, they kill tumor cells).

Targeted therapies are currently the focus of intense anti-cancer drug development. Spending on targeted therapies continues to grow rapidly in all regions of the world and now represents 48% of total oncology spending, up 36% from 2010. As mentioned above, we are focused on targeted therapies for cancer treatment with TTX-MC138 as an example.

Immunotherapy

Immunotherapy has become an established pillar of cancer treatment improving the prognosis of many patients with a broad variety of hematological and solid malignancies. The two main drivers behind this success are checkpoint inhibitors, or CPIs, and chimeric antigen receptor, or CAR, T cells. For checkpoint blockade, current studies focus on combinational approaches, perioperative use, new tumor entities, response prediction, toxicity management and use in special patient populations. Regarding cellular immunotherapy, recent studies confirmed safety and efficacy of CAR T cells in larger cohorts of patients with acute lymphoblastic leukemia or diffuse large B cell lymphoma. Different strategies to translate the striking success of CAR T cells in B cell malignancies to other hematological and solid cancer types are currently under clinical investigation. Regarding the regional distribution of registered clinical immunotherapy trials, a shift from PD-1 / PD-L1 trials (mainly performed in the U.S. and in the European Union, or EU) to CAR T cell trials (majority of trials performed in the United States and China) can be noted.

The importance of immunotherapy is underscored by the fact that the Nobel prize for physiology and medicine in 2018 was awarded to James P. Allison and Tasuku Honjo for the discovery of cytotoxic T-lymphocyte-associated protein, or CTLA-4, and programmed cell death protein1 / programmed cell death protein ligand 1, or PD-1 / PD-L1. Malignant tumors take advantage of the inhibitory PD-1 / PD-L1 or CTLA-4 pathways to evade the immune system. Disrupting this axis by blocking monoclonal antibodies can induce durable remissions in different cancer types and has led to numerous FDA and European Medicines Agency, or EMA, approvals, among others, for the treatment of melanoma, lung cancer, urothelial cancer, head and neck squamous cell carcinoma, or HNSCC, renal cell carcinoma, or RCC, and Hodgkin's disease.

Tyrosine kinase inhibitors

Tyrosine kinase inhibitors are targeted therapies for cancer. Although some tyrosine kinase inhibitors are used to treat other types of cancer, lapatinib (Tykerb) is the only one that is FDA-approved for the treatment of breast cancer. Lapatinib is only used to treat HER2-positive metastatic breast cancer.

PARP inhibitors

Poly (ADP-ribose) polymerase, or PARP, inhibitors are a class of drugs under study for many types of cancer, including breast cancer. PARP is an enzyme involved in DNA repair. At this time, PARP inhibitors are only offered in clinical trials for people with metastatic breast cancer. Early findings suggest that PARP inhibitors hold the most promise for people with metastatic breast cancer who have a BRCA1 or BRCA2 gene mutation.

Cyclin dependent kinase 4 and 6 (CDK4/6) inhibitors

CDK4 and CDK6 are enzymes important in cell division. CDK4/6 inhibitors are a new class of drugs designed to interrupt the growth of cancer cells. The CDK4/6 inhibitor palbociclib (Ibrance) in combination with hormone therapy is FDA-approved for the treatment of hormone receptor-positive, HER2-negative metastatic breast cancers.

PI3 kinase inhibitors

PI3 kinase is an enzyme important in cell growth. The PIK3CA gene helps control PI3 kinase enzyme activity. Some breast cancers have a mutation in the PIK3CA gene, and this mutation can affect PI3 kinase and cause the tumor to grow. PI3 kinase inhibitors are a new class of drugs designed to interrupt PI3 kinase signals and stop the growth of cancer cells. PI3 kinase inhibitors are under study for the treatment of metastatic breast cancer.

Seviprotimut-L Competition

The competitive landscape for Seviprotimut-L in resected stage II/III melanoma is dominated by adjuvant immunotherapies and targeted agents, with emerging modalities further intensifying competition. Seviprotimut-L is an allogeneic, polyvalent, partially purified shed melanoma antigens vaccine (alum adjuvanted) derived from three proprietary human melanoma cell lines designed to prevent recurrence in patients with resected high-risk melanoma (stage II–III). Seviprotimut-L has demonstrated a favorable safety profile and has shown potential benefit in select subgroups, such as stage IIB/IIC patients.

Immune checkpoint inhibitors currently represent the standard of care, demonstrating significant improvements in recurrence-free survival. Two checkpoint inhibitors that have shown efficacy for the adjuvant treatment of melanoma in Stage IIB and IIC patients at risk for disease recurrence, Keytruda (from Merck) and Opdivo (from Bristol Myers Squibb) have both been approved.

Additionally, targeted therapies (e.g., BRAF/MEK inhibitor combinations like dabrafenib + trametinib) provide an effective option for biomarker-selected stage III patients.

Beyond established therapies, personalized neoantigen vaccines, oncolytic viruses, and tumor-infiltrating lymphocyte (TIL) therapies, are entering the immunotherapy landscape.

Overall, we believe that Seviprotimut-L occupies a niche as a well-tolerated vaccine targeting recurrence prevention with likely differentiation on safety and tolerability.

Competition to Oncolytic Viruses targeting MIBC

The current gold standard for the treatment of localized MIBC involves neoadjuvant cisplatin-based chemotherapy followed by radical cystectomy and pelvic lymph node dissection. However, novel treatment alternatives in the neoadjuvant setting, in particular, bladder-sparing treatments, are urgently needed because more than 50% of patients are ineligible for standard cisplatin-based neoadjuvant chemotherapy. Currently, immune checkpoint inhibitors (ICIs), antibody drug conjugates (ADCs), and targeted therapies are as described below.

Preclinical stage:

Adenovirus XVir-N-31 (Ad-Delo3-RGD): oncolytic adenovirus vector dl520 that was rendered cancer-specific by deletion of the transactivation domain CR3 of the adenoviral E1A13S protein; this deletion causes antitumor activity in drug-resistant cells displaying nuclear YB-1 expression.

Alphavirus M1: naturally occurring, non-pathogenic Getah-like virus isolated from mosquitoes that demonstrates strong oncolytic properties.

Personalized peptide-based vaccines targeting tumor mutations and *in situ* vaccines using radiation combined with checkpoint inhibitors.

Clinical Stage:

Several recruiting clinical studies investigating ADCs or bispecific antibodies in combination with immune checkpoint inhibitors (anti-PD-1 or PD-L1) in cisplatin-ineligible MIBC patients.

Approved and commercialized:

Durvalumab (anti-PD-L1, IgG, IMFINZI®) in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by IMFINZI® as adjuvant monotherapy after radical cystectomy for the treatment of MIBC patients.

CHEMISTRY, MANUFACTURING AND CONTROLS (CMC)

CMC is an extensive aspect of the IND-enabling process and is critical to setting appropriate timelines and connecting "deliverables" to clinical trials. The term "deliverables" refers to more than just the drug product itself. It also includes analytical standards and required documentation on drug purity, dose strength, storage, handling and stability. Materials for the analytical development process produced as part of the CMC process must be delivered before CMC development work can begin, as are activities that require analytical support for which time requirements must also be considered.

The design and manufacture of therapeutic candidates such as TTX-MC138 for miRNA targeting in tumor cells has gone through extensive research and development optimization at MGH prior to our company formation. Optimization work continues in our lab and at our CMO. The oligonucleotide drug substance incorporated in the final therapeutic candidate drug product is currently manufactured by our contract manufacturer, or CMO, in Germany. We believe this CMO will be able to meet our needs for oligonucleotide manufacturing meeting current good manufacturing practices, or cGMP, or good laboratory practices, or GLP, (together sometimes referred to as GxP) at least for the near term. TransCode has been utilizing the manufacturing services of this CMO since 2017.

We engaged a different European CMO to produce the final therapeutic candidate drug product.

COMMERCIALIZATION

We retain worldwide commercialization rights for our key therapeutic and diagnostic candidates. We currently have no sales, marketing or product distribution capabilities. However, if our therapeutic candidates appear closer to FDA approval, we may explore commercialization partnerships with larger pharmaceutical organizations or out-license sales and marketing of those therapeutic candidates.

We also intend to consider opportunities to license certain of our technologies to other companies with an oncology focus. Our commercial plans and strategy for each particular program may change as programs advance, markets change, we obtain more clinical data, and we assess our capital requirements.

GOVERNMENT REGULATION

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs. We, along with our vendors, contract research organizations and contract manufacturers, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our therapeutic candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, where we are initially focusing our drug development activities, the FDA regulates drug products under the Federal Food, Drug and Cosmetic Act, or FD&C Act, and biological products, or biologics, under the Public Health Service Act, or PHSA, and the FD&C Act, and its implementing regulations and other laws. Our therapeutic candidates are in early-stage preclinical

and clinical development and none of our therapeutic candidates has been approved by the FDA for marketing in the United States. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other legal requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences.

These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, suspension or revocation of approved applications, FDA Form 483s, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before our therapeutic candidates are approved as drugs or biologics for therapeutic indications and for marketing in the United States generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin;
- approval by an IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of a New Drug Application, or NDA;
- preparation and submission to the FDA of a Biologics License Application, or BLA, for a biologic product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product and proposed labeling;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA, to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with current good manufacturing practices, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practice, or CGTP, for the use of human cellular and tissue products;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our therapeutic candidates will be granted on a timely basis, if at all.

Preclinical and clinical trials for drugs and biological products

Before testing any drug or biological product in humans, the therapeutic candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical

studies, together with manufacturing information and analytical data must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the content of the IND or clinical trial design, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development of a therapeutic candidate, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

The clinical stage of development involves the administration of the therapeutic candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection, inclusion and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable related to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Sponsors of applicable clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information within specific timeframes for publication on the www.clinicaltrials.gov website. Sponsors also must disclose certain results of these clinical trials, although disclosure of results may be delayed until after the new product or new indication has been approved by the FDA. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs, as well as clinical trial design. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to public notifications of noncompliance, civil monetary penalties, and also prevent the non-compliant party from receiving future grant funds from the federal government.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor must submit data from the clinical trial to the FDA in support of an NDA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs or BLAs for marketing approval generally could be conducted in three sequential phases, which may overlap.

- *Phase 1* — Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- *Phase 2* — Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.

- *Phase 3* — Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labelling.

FDA additionally allows for the conduct of exploratory IND studies, termed Phase 0 clinical trials. Exploratory IND trials are conducted under an IND early in clinical development, prior to traditional dose escalation, safety and tolerance studies that ordinarily initiate a clinical drug development program. Exploratory IND studies usually involve very limited human exposure and have no therapeutic or diagnostic intent. The goals of an exploratory IND study may include determining whether a mechanism of action defined in experimental systems can also be observed in humans, providing important information on pharmacokinetics, selecting the most promising lead product from a group of candidates designed to interact with a particular therapeutic target in humans, based on pharmacokinetic or pharmacodynamic properties, or exploring a product's biodistribution characteristics using various imaging technologies.

In March 2022, the FDA released final guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development (i.e., the First-in-Human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce developmental costs and time.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the clinical protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the therapeutic candidate. Companies must also finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the therapeutic candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the therapeutic candidate does not undergo unacceptable deterioration over its shelf life.

U.S. marketing approval for drugs and biological products

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. An NDA is a request for approval to market a new drug for one or more specified indications and must contain proof of the drug's safety and efficacy. A BLA seeks approval to market a biologic and must demonstrate the product's safety, purity, and potency. In all cases, the marketing application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of an NDA or BLA must be obtained before a drug or biological product, respectively, may be marketed in the United States.

The FDA has 60 days after submission of the NDA or BLA application to conduct an initial review to determine whether it is sufficient to accept for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. FDA may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the

submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA or BLA. The FDA reviews an NDA or BLA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Similarly, under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure, and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure, and potent. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten months from the filing date to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA or BLA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for approved and marketed biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk-minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the Sponsor product within required specifications. Additionally, before approving an NDA or BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the NDA or BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA or BLA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug or biological product with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's or biologic's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

U.S. patent term restoration and regulatory data exclusivity

In certain circumstances, some U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments. Patent term restoration is intended to compensate for patent life lost during product development and the FDA review process and may extend a patent term by

up to five years, subject to a maximum remaining patent term of 14 years from the product's approval date. Only one patent per approved product may be eligible for such restoration, and any application for patent term restoration must be submitted prior to patent expiration. The U.S. Patent and Trademark Office, in consultation with the FDA, determines eligibility for patent term restoration.

Certain drug products may also qualify for periods of non-patent regulatory data exclusivity. A drug product containing an active ingredient not previously approved by the FDA is generally entitled to five years of regulatory data exclusivity. Products approved based on the FDA's reliance on new clinical investigations essential to approval may receive three years of regulatory data exclusivity. If pediatric studies are conducted in response to an FDA request, pediatric exclusivity may be granted, which for drugs extends existing patent and regulatory exclusivities by six months and for biologics extends existing regulatory exclusivities by six months.

The Biologics Price Competition and Innovation Act of 2009 established an abbreviated licensure pathway for biological products demonstrated to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. A biosimilar product must be shown to be highly similar to the reference product and to have no clinically meaningful differences in safety, purity, or potency. An interchangeable product must additionally be shown to produce the same clinical result in any given patient and, for products administered more than once, to be capable of alternating or switching with the reference product without increased risk. A reference biological product is entitled to 12 years of regulatory data exclusivity from the date of first licensure, and the FDA may not accept an application for a biosimilar or interchangeable product until four years after that date.

Orphan drug designation and exclusivity

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to a therapeutic candidate intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan Drug Designation must be requested before submitting an NDA or BLA. Orphan Drug Designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

If a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to Orphan Drug Exclusivity, a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same approved use or indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. Orphan Drug Exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same approved use or indication before we do, unless we are able to demonstrate that our product is clinically superior. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to Orphan Drug Exclusivity. Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Rare pediatric disease designation and priority review vouchers

Under the FD&C Act, the FDA incentivizes the development of drugs that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug for such disease or condition will be received from sales in the United States of such drug. The sponsor of a therapeutic candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug application after the date of approval of the rare pediatric disease drug product, referred to as a priority review voucher, or PRV. A sponsor may request rare pediatric disease designation from the FDA prior to submission of its BLA. The sponsor of an application for a rare pediatric disease drug product may be eligible for a voucher that can be used or sold to obtain a priority review for a subsequent

application submitted under section 505(b)(1) of the FD&C Act or section 351 of the PHSA. Designation of a drug or biological product as a product for a rare pediatric disease does not guarantee that a marketing application for such product will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Moreover, a sponsor who chooses not to submit a rare pediatric disease designation request may nonetheless receive a PRV upon approval of their marketing application if they request such a voucher in their original marketing application and meet all of the eligibility criteria. If a PRV is received, it may be sold or transferred an unlimited number of times. Under current law, after September 30, 2029, FDA may not award any rare pediatric disease priority review vouchers, although FDA's authority to do so could be extended by Congress in the future.

Expedited development and review programs for drugs and biological products

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs addressing unmet medical needs or for treating serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval. The purpose of these programs is to expedite either the development or the review of certain new drugs or biologics to get them to patients sooner than under standard FDA development and review procedures. TransCode anticipates seeking one or more of these qualifications or designations, but there is no assurance that any will be obtained and even if obtained, that TransCode will be able to maintain those designations.

A new drug or biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as Priority Review, discussed below. In addition, a new drug or biologic may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and accelerated approval. A product is eligible for Priority Review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA must review an application in six months compared to ten months for a standard review. Additionally, products are eligible for accelerated approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Accelerated approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, unless otherwise informed by the FDA, the FDA currently requires, as a condition for accelerated approval, that all advertising and promotional materials that are intended for dissemination or publication within 120 days following marketing approval be submitted to the agency for review during the pre-approval review period, and that after 120 days following marketing approval, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or review process.

Pediatric information and pediatric exclusivity

Under the Pediatric Research Equity Act, or PREA, certain NDAs or BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug or biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FD&C Act to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

A drug or biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms for small molecule drugs, and six months to existing exclusivity periods for biological products. This six-month exclusivity, which runs from the end of other exclusivity protection (or patent term, for small molecule drugs), may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

U.S. post-approval requirements for drugs or biologics

Drugs or biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or BLA or supplement thereof, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug and biological product manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our contract manufacturers. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, FDA Form 483s, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or mandated modification of promotional materials and labeling and issuance of corrective information.

FDA Regulation of In Vitro Diagnostics

In vitro diagnostics, including companion diagnostics and complementary diagnostics, are regulated as medical devices by FDA. In the United States, the FD&C Act, and its implementing regulations and other federal and state statutes and regulations, govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance or approval from FDA prior to commercialization. The two primary types of FDA marketing authorization applicable to a medical device are clearance of a premarket notification, or 510(k), and approval of a premarket approval application, or PMA.

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have previously received 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a pre-amendment device that was in commercial distribution before May 28, 1976, or a predicate device, for which the FDA has not yet called for the submission of a PMA. In making a determination that the device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device and assesses whether the subject device is comparable to the predicate device with respect to intended use, technology, design and other features which could affect safety and effectiveness. If the FDA determines that the subject device is substantially equivalent to the predicate device, the subject device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer.

A PMA must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the quality management system regulation, or QMSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA's review of an initial PMA is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If FDA evaluations of both the PMA and the manufacturing facilities are favorable, FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If FDA's evaluation of the PMA or the manufacturing facilities is not favorable, FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

Companion diagnostics identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. On July 31, 2014, FDA issued a final guidance document addressing the development and approval process for "*In Vitro* Companion Diagnostic Devices." According to the guidance document, for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for the safe and effective use of the corresponding therapeutic product, the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic, although FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, FDA's guidance indicates it will generally not approve the drug without the approval or clearance of the diagnostic device. FDA also issued draft guidance in July 2016 setting forth the principles for co-development of an *in vitro* companion diagnostic device with a therapeutic product. The draft guidance describes principles to guide the development and contemporaneous marketing authorization for the therapeutic product and its corresponding *in vitro* companion diagnostic.

The use of the companion diagnostic device will be stipulated in the labeling of the therapeutic product. This is also true for a complementary diagnostic, although it is not a prerequisite for receiving approval of the therapeutic as is generally the case with companion diagnostics.

Once cleared or approved, an *in vitro* diagnostic device, including a companion diagnostic or complementary diagnostic, must adhere to post-marketing requirements including the requirements of FDA's quality system regulation, adverse event reporting, recalls and corrections along with product marketing requirements and limitations. Like drug makers, *in vitro* diagnostic makers are subject to unannounced FDA inspections at any time during which FDA will conduct an audit of the product(s) and the company's facilities for compliance with its authorities.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities of therapeutic candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Other Healthcare Laws

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

- The federal civil and criminal false claims laws, including the civil False Claims Act, or FCA, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistle-blower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.

- The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies.

- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers such as physician assistants and nurse practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In addition, many states also require reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

- Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. These laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts.

State and foreign laws also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts. California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General will commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

Insurance Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a therapeutic candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, therapeutic candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and consolidated financial condition. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other

payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Current and Future Healthcare Reform Legislation

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the Affordable Care Act, which, among other things, includes changes to the coverage and payment for products under government health care programs. The Affordable Care Act includes provisions of importance to our potential therapeutic candidates that:

- created an annual, non-deductible fee on any entity that manufactures, or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- increased the minimum level of Medicaid rebates payable by manufacturers of brand new drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations; and
- required manufacturers to participate in a coverage gap discount program, later replaced under the Inflation Reduction Act of 2022 by the Medicare Part D manufacturer discount program under which manufacturers must agree to offer a 50% point-of-sale discount (later increased to 70%) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; among other reforms.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act, or ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court and members of Congress have introduced several pieces of legislation aimed at significantly revising or repealing the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. The Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which will remain in effect through 2031 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Inflation Reduction Act of 2022, or IRA, includes several provisions that have the potential to impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs in Medicare Part D, allow the United States government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one or more orphan designation(s) and for which the only approved indication(s) is for a rare disease or condition. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. The Trump Administration has issued executive orders and supported proposed regulatory initiatives in 2025 that could have a significant impact on the prices that we, or any collaborators, may receive for any approved products.

On May 12, 2025, President Trump signed an executive order directing the Secretary of HHS to set and communicate most-favored-nation ("MFN") price targets to manufacturers and propose a rulemaking plan to impose MFN pricing if "significant progress" is not made, and also directing the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. The executive order further states that the Administration will take additional action (for example, examining whether marketing approvals should be modified or rescinded or considering individual drug importation waiver authorities) should manufacturers fail to offer American consumers the MFN lowest price. In July 2025, President Trump sent letters to certain pharmaceutical companies demanding that these companies extend MFN pricing to Medicaid and newly launched drugs as well as move to direct-to-consumer models priced at MFN pricing, and soliciting binding commitments by September 29, 2025. Since this time, multiple drug manufacturers have announced plans to, for certain of their drugs, lower prices to reflect similar pricing around the world, and to sell these reduced-price drugs on a direct-to-consumer purchasing platform developed by the federal government; however, it is not known what results will occur to the extent the recipients of these letters do not reduce their U.S. prices.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025,

CMS introduced the GENErating cost Reductions fOr U.S. Medicaid ("GENEROUS") Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, consolidated financial condition, consolidated results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs (if approved for marketing) or put pressure on our drug pricing, which could negatively affect our business, consolidated financial condition, consolidated results of operations and prospects.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union, or EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular therapeutic candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the EU provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

Recently, many countries in the EU have increased the discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Compliance with other federal and state laws or requirements; changing legal requirements

If any products that we may develop are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, labeling, packaging, distribution, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to which we may be subject.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply

contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

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

Other U.S. environmental, health and safety laws and regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third-parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Government regulation of drugs outside the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization or identification of an alternate regulatory pathway, manufacturing, commercial sales and distribution of our products. For instance, in the EU, medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

Centralized procedure — If pursuing marketing authorization of a therapeutic candidate for a therapeutic indication under the centralized procedure, following the receipt of an opinion from the European Medicines Agency's, or EMA, Committee for Medicinal Products for Human Use, or CHMP, the European Commission issues a single marketing authorization valid across the EU (and in the additional countries of the European Economic Area, or EEA, which is comprised of the EU member states plus Iceland, Liechtenstein and Norway). The centralized procedure is compulsory for human medicines derived from biotechnology processes or advanced therapy medicinal products (i.e. gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, or viral diseases, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EU, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EU. Under the centralized procedure the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the

evaluation of a marketing authorization application under the accelerated assessment procedure is 150 days, excluding clock stops.

- *National authorization procedures* — There are also two other possible routes to authorize products for therapeutic indications in several countries in the EU, which are available for products that fall outside the mandatory scope of the centralized procedure:

- *Decentralized procedure* — Under the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country.

- *Mutual recognition procedure* — In the mutual recognition procedure, a medicine is first authorized in one EU country, in accordance with the national procedures of that country. Following this, additional marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

In the EU, innovative medicinal products that are authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. In the EU, a medicinal product may be designated as orphan if its sponsor can demonstrate that (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved orphan indication. During this ten-year orphan market exclusivity period, no marketing authorization application shall be accepted, and no marketing authorization shall be granted for a similar medicinal product for the same indication as an authorized orphan product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan product can also obtain an additional two years of market exclusivity in the EU for completion of pediatric studies in compliance with a pediatric investigation plan agreed with the EMA. The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar medicinal product for the same indication as an authorized orphan product at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized product consents to a second medicinal product application; or (iii) the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product.

Similar to the United States, the various phases of non-clinical and clinical research in the European Union are subject to significant regulatory controls.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation No 536/2014, or CTR, which repealed the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, or CTIS, which contains a centralized EU portal and database.

While the Clinical Trials Directive required a separate CTA to be submitted in each member state, in which the clinical trial was to take place, to both the national competent authority and an independent ethics committee, much like the FDA and IRB respectively, for each clinical trial, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials through the CTIS. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state in which the trial is to take place, leading to a single decision per member state. The assessment of applications for clinical trials is divided into two parts (Part I contains scientific and medicinal product-related documentation and Part II contains national and patient-level documentation). Part I is subject to a coordinated review by competent authorities of all EU member states in which an application for authorization has been submitted (member states concerned). One of the member states concerned (the reporting member state) prepares a draft assessment report which is submitted to other member states concerned for their joint review, allowing for a single assessment report to be issued at the term of the assessment process. Part II is assessed separately by each member state concerned. The role of the relevant ethics committees in the assessment procedure continues to be governed at national level, however overall related timelines are set out under the CTR. The CTR also provides for simplified reporting procedures for clinical trial sponsors.

The aforementioned EU rules are generally applicable in the EEA.

The collection and use of personal health data in the European Union, previously governed by the provisions of the Data Protection Directive, is now governed by the General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. While the Data Protection Directive did not apply to organizations based outside the EU, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the EU. This expansion would incorporate any clinical trial activities in EU members states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer "adequate" privacy protections. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States, which may deviate slightly from the GDPR, may result in fines of up to 4% of global revenues, or €20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance are onerous and may adversely affect our business, financial condition, results of operations and prospects.

Should we utilize third-party distributors, compliance with such foreign governmental regulations would generally be the responsibility of such distributors, who may be independent contractors over whom we have limited control.

Reform of the Pharmaceutical Regulatory Framework in the EU

The EC introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the European Union adopted its position. A common position on the text was agreed upon on December 11, 2025, in the context of subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be adopted into EU law, and are not expected to become applicable before 2028.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom, or UK, left the EU on January 31, 2020, commonly referred to as "Brexit", and pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020. The UK and the EU have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations.

Following the end of the Brexit transition period on January 1, 2021 and the implementation of the Windsor Framework on January 1, 2025, the UK is no longer generally subject to EU law in respect of medicines. EU laws that were transposed into UK law by secondary legislation continue to apply in the UK where retained, but new EU legislation (for example, the EU CTR) is not directly applicable in the UK.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the UK's standalone medicines and medical devices regulator. As a result of the Northern Ireland Protocol, different rules applied in Northern Ireland than in England, Wales, and Scotland, which, prior to January 1, 2025, continued in certain respects to follow elements of the EU regulatory regime. However, on January 1, 2025, a new arrangement called the "Windsor Framework" came into effect. The Windsor Framework provides for UK-wide marketing authorizations granted by the MHRA and replaces prior EU centralized marketing authorization applicability in Northern Ireland with specific UK labeling and supply requirements. A single UK-wide marketing authorization will be granted by the MHRA for all novel medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. In addition, for packs placed on the UK market on or after January 1, 2025, the new arrangements require a "UK Only" label indicating that they are not for sale in the EU.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, which implemented the EU Clinical Trials Directive (2001/20/EC) into UK law through secondary legislation. In April 2025, the UK introduced the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025; these changes, due to take effect in April 2026, aim to create a streamlined, risk-proportionate system to accelerate approvals while maintaining safety standards.

EMPLOYEES AND HUMAN CAPITAL RESOURCES

As of April 3, 2026, we had 12 employees, all of whom are full-time. Seven employees are engaged primarily in research and development, clinical and quality systems, and five are engaged primarily in business development, corporate strategy, finance, and general management and administration. Our employees work at locations in six states. We supplement the efforts of our employees by use of consultants and advisors. None of our employees is represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good. Our human capital is integral to helping us achieve our goal to change how cancer is treated both as a therapeutic modality and in terms of improving patient outcomes. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and future employees. The principal purposes of our equity incentive plans are to attract, retain and motivate our employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

AVAILABLE INFORMATION

Our website address is https://www.transcodetherapeutics.com where we make available free of charge our Forms 10-K, 10-Q, and our current reports on Form 8-K, including exhibits, and amendments to those reports, as soon as reasonably practicable after they are filed with or furnished to the SEC.

ITEM 1A. 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, as well as the other information in this annual report. Our business, prospects, consolidated financial condition, or consolidated 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, consolidated financial condition or consolidated 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." 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 consolidated financial position and need for additional capital

We could lose our listing on the Nasdaq Capital Market if we do not maintain our stockholders' equity or if the closing bid price of our common stock does not increase or if we do not comply with other Nasdaq requirements. The loss of our Nasdaq listing would in all likelihood make our common stock significantly less liquid and adversely affect its value, including a total loss of value.

As disclosed in various Current Report on Form 8-K filings with the SEC, at times we have not been in compliance with various Nasdaq rules for continued listing of our stock on the Nasdaq Capital Market, LLC, or Nasdaq. We have received letters from the Listing Qualifications Department, or the Staff, of Nasdaq stating that we were not in compliance with certain requirements for continued listing on the Nasdaq Capital Market. In most of these instances, we appealed the delisting determinations to Nasdaq Hearing Panels where we received extensions of time to regain compliance and maintain our Nasdaq listing. However, there is no assurance that in the event we do not meet Nasdaq listing requirements, we will receive any extensions of time to regain compliance and maintain our Nasdaq listing in which case our stock would be delisted from trading on Nasdaq.

In the event of 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 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, many institutional investors are prohibited from investing in OTC stocks, and it might be more challenging to raise capital when needed. We may need to seek an in-court or out-of-court restructuring of our liabilities. In the event of such restructuring activities, holders of our common stock and other securities will likely suffer a total loss of their investment.

We have identified conditions and events that raise substantial doubt about our ability to continue operations in the near-term and our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. We may need to seek an in-court or out-of-court restructuring of our liabilities, including potentially a bankruptcy proceeding, or to substantially reduce or totally cease our operations.

We may be forced to amend, delay, limit, reduce or terminate the scope of our development programs and/or limit or cease our operations if we are unable to obtain additional funding. As of December 31, 2025, we had cash of approximately $17.8 million. We believe that these funds will support our operating expenses and capital requirements through approximately year end 2026. On April 7, 2026, we entered into a financing agreement with an affiliate of Yorkville Advisors ("Yorkville"). Under this agreement, we expect to issue to Yorkville up to $6 million of convertible notes ("Convertible Notes") and we have the option to sell to Yorkville up to $14 million of our Common Stock pursuant to the Standby Equity Purchase Agreement (the "SEPA") between us and Yorkville. Each of these financings is subject to certain conditions. Unless we obtain the approval of our stockholders, we may not receive the proceeds from the $5 million Second Convertible Note (as defined below). Further, if more than 10% of the Convertible Notes remain outstanding, we will not be able to require Yorkville to purchase our shares of Common Stock pursuant to the SEPA.

Our recurring consolidated losses from operations and negative consolidated 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 consolidated financial statements for the years ended December 31, 2025 and 2024, with respect to this uncertainty. Our ability to continue as a going concern is dependent on our available cash, how well we manage that cash, and our operating requirements. We will need to raise additional capital to continue as a going concern. The failure to obtain

sufficient additional funds on commercially acceptable terms to fund our operations and satisfy our obligations to creditors may have a material adverse effect on our business, consolidated results of operations and consolidated financial condition and jeopardize our ability to continue operations in the near-term. We will likely need to consider additional cost reduction strategies, which may include, among others, amending, delaying, limiting, reducing, or terminating our development programs, and we may need to seek an in-court or out-of-court restructuring of our liabilities, including potentially a bankruptcy proceeding, or to substantially reduce or totally cease our operations. In the event of such future restructuring activities, holders of our common stock and other securities will likely suffer a total loss of their investment.

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

Investment in oncology product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential therapeutic candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. We are still in the early stages of development for most of our therapeutic candidates. In October 2025, we completed and announced results for our Phase 1a clinical trial with TTX-MC138. Also in October 2025, we acquired Seviprotimut-L, a novel polyvalent shed antigens vaccine for the potential adjuvant treatment of melanoma, that has completed Phase 2 clinical development. We have no products licensed for commercial sale and have not generated any revenue from product sales or otherwise to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We finance our current operations with funds obtained primarily from equity financings.

We have incurred significant annual net losses since inception. For the years ended December 31, 2025 and 2024, our net losses were approximately $34.7 million and $16.8 million, respectively. As of December 31, 2025, our accumulated deficit was approximately $97.9 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

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

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

our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on stockholders' equity (deficit).

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

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

- initiating and completing research regarding preclinical and clinical development of TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526 and any future therapeutic candidates;
- developing a sustainable and scalable manufacturing process for TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526 or our other therapeutic candidates and any future therapeutic candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third-parties;
- launching and commercializing TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526, our other therapeutic candidates and any future therapeutic candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526 our other therapeutic candidates and any future therapeutic candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new therapeutic candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining, maintaining, attempting protection of, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

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

If in the future we obtain regulatory approvals to market TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526 or other therapeutic candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the price for the product we obtain, the ability to obtain reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for our current therapeutic candidates and any future therapeutic candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate sufficient revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

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

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

The development of pharmaceutical drugs and biological products is capital intensive. As of December 31, 2025, we had cash totaling approximately $17.8 million. We believe that these funds will be sufficient to support our operating expenses and capital expenditure requirements through approximately year end 2026. As a result, we will need to raise additional capital to continue as a going concern. Unless we receive additional funding, we may not be able to complete clinical trials we begin. Further, 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.

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, biological product candidate discovery, preclinical development, laboratory testing and clinical trials for our current or future therapeutic candidates;
- 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, manufacturing, 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 other 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 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, consolidated 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, consolidated financial condition and consolidated results of operations.

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

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

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

- general market conditions or extraordinary external events, such as a recession, civil uprisings or military conflicts;
- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

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

Risks related to research and development and the biopharmaceutical industry

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

We are a clinical-stage oncology company with a limited operating history. We commenced operations in 2016, and until our IPO, our operations were limited to organizing and staffing our company, business planning, raising capital, conducting limited discovery and research activities, filing patent applications, identifying potential therapeutic candidates, undertaking preclinical studies and preparing for clinical trials, process development and manufacturing of initial quantities of our therapeutic candidates and component materials. Our lead therapeutic candidate, TTX-MC138, is currently in the early stages of clinical development. We acquired Seviprotimut-L, a novel polyvalent shed antigens vaccine for the potential adjuvant treatment of melanoma, which has completed Phase 2 clinical development. We have not yet demonstrated our ability to successfully complete large-scale later-stage clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third-party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

We are unable to predict the full range of risks that may emerge, and we cannot guarantee that we will meet or achieve the clinical or commercial results we expect. The future of our business depends on us successfully developing, obtaining marketing approval for, and marketing profitably our therapeutic candidates. This requires many complex scientific activities, successful pursuit of regulatory approvals, appropriate market assessments, the strategic management of intellectual property and financial resources and effective management of many other aspects of our business. Products for which we receive regulatory approval must demonstrate safety and efficacy. Competitively, the products must improve patient outcomes, deliver benefits to intended customers, maintain an affordable price, and be superior to competitive products. To be successful, we must also be effective in driving awareness of our therapeutics to achieve market adoption for our approved products and to be profitable. The risks of missteps, setbacks, errors and failings with respect to any aspect of managing our business are an inherent part of attempted innovation in the life sciences industry. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may materially and adversely affect our business.

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

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

In drug and biologic development, there is a high risk of failure and we may never succeed in developing marketable products or generating therapeutic revenues.

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

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

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

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

We also face the risk of:

- competitors introducing technologies which render our development efforts or approved products obsolete;
- data from our clinical trials not being strong enough to support therapeutic approval or the marketing claims needed for market success and to achieve our financial projections;
- granting oversight of our clinical trials' conduct, results, and compliance to an organization or investigator under an IND other than our own IND; and
- being unable to manufacture or supply, or have manufactured or supplied on our behalf, approved products cost-effectively.

Our business is highly dependent on the success of TTX-MC138, our lead candidate, as well as our other product candidates, including Seviprotimut-L, UIO 524, UIO 525, and UIO 526. All of our therapeutic candidates may require significant additional manufacturing, preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. Most of our development effort are at early stages; only two of our therapeutic candidates, TTX-MC138 and Seviprotimut-L, have reached clinical development. In October 2025, we completed and announced results for our Phase 1a clinical trial with TTX-MC138. Also in October 2025, we acquired Seviprotimut-L, a novel polyvalent shed antigens vaccine for the potential adjuvant treatment of melanoma, that has completed Phase 2 clinical development. If we are unable to successfully develop, obtain regulatory approval for, and commercialize our therapeutic candidates, or we experience significant delays in doing so, our business will be materially harmed. Advancing our therapeutic candidates will require substantial investment before we can seek regulatory approval and potentially launch commercial sales. Further development of our therapeutic candidates will require production scaleup, clinical studies, regulatory review and approval in the U.S. and other jurisdictions, development of sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales, if ever.

In developing TTX-MC138 or any of our other current or future product candidates, among other risks, we may not be successful in synthesizing or producing the components of our proprietary formulations, there may be toxicology issues from key components of our formulations that we have not anticipated, or we may encounter other problems. We have not manufactured TTX-MC138 using

the current synthesis protocol, production processes, equipment and materials in the larger quantities that would be necessary to meet clinical trial treatment demands for all anticipated patients.

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

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

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

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.

Undesirable side effects or death caused by any of our therapeutic candidates could cause IRBs, our contract research organizations, or CROs, the FDA or other regulatory authorities to interrupt, delay or discontinue clinical trials and could result in the denial of regulatory approval for our therapeutic candidates. This, in turn, could prevent us from commercializing our therapeutic candidates and generating revenues from their sale. Immunotherapy, and its method of action of harnessing the body's immune system, is powerful and could lead to serious side effects that we only discover in clinical trials. Unforeseen side effects could arise either during clinical development or, if such side effects are rare, after our product candidates have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients.

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

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

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

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

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.

To obtain the requisite regulatory approvals to commercialize any therapeutic candidates, we must demonstrate through extensive preclinical studies and clinical trials that our therapeutic candidates are safe and effective in humans. Clinical trials are expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A therapeutic candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or clinical trials. The results of preclinical studies and early clinical trials of our therapeutic candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of therapeutic candidates proceeding through clinical trials. Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology and biopharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most therapeutic candidates that commence clinical trials are never approved as therapeutic products, and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526 or any of our other therapeutic candidates.

Therapeutic candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

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

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Our FIH clinical trial with radiolabeled TTC-MC138 was designed as a single microdose trial, the purpose of which was to demonstrate safety and proof of delivery of TTX-MC138 to metastatic lesions. This design was not meant or expected to produce efficacy signals or to show that TTX-MC138 reaches into metastatic tumor cells. Our open Phase I/II clinical trial with TTX-MC138 is a Bayesian Optimal Interval Design, or BOIN design, with dose escalation and expansion. Key assessments in the clinical trial characterize the safety, pharmacokinetic, pharmacodynamic and anti-tumor activity thus identifying a maximum tolerated dose (MTD) and ensuring the mechanism of action is on target. The study also is exploring the effect of TTX-MC138 on biomarker expression, which may include miR-10b expression, and miR-10b downstream targets (ribonucleic acid, or RNA, sequencing). Clinical assessments to further evaluate TTX-MC138 include clinical laboratory exams, CT scan assessments, and response assessments per RECIST. In October 2025, we completed and announced results for our Phase 1a clinical trial with TTX-MC138.

Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their therapeutic candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.

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

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

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

Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each therapeutic candidate and, consequently, the ultimate approval and commercial marketing of any therapeutic candidates.

We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business.

Caution should be taken when interpreting the preliminary results of our preclinical studies or clinical trials, including those for TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526, or any of our other product candidates. These data may differ from future results of additional studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data. These results and related findings and conclusions are subject to change following more comprehensive reviews of the data related to the particular study or trial. We also may make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, preliminary or topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated.

Interim data from studies or clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available or as patients from our clinical trials continue other treatments for their disease. The final results of the trial may not be as positive as the interim data and these differences could be meaningful. Topline data from completed studies remain subject to audit and verification procedures that may result in the final data being materially different from the topline data we previously published. As a result, preliminary and topline data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically based on extensive data, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, preliminary or topline data that we report differs from subsequent results, or if others, including regulatory authorities, disagree with the conclusions we reach, our ability to seek and obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, consolidated operating results, prospects or consolidated financial condition. In addition, disclosure of interim, preliminary or topline data by us or by our competitors could result in volatility in the price of our common stock.

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

We may experience difficulties in patient enrollment in our clinical trials for many reasons. The number of qualified clinical trial investigators and sites is limited. We expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use. This could reduce the number of patients available for our clinical trials at such clinical trial site. Clinical trials of

other companies may be in similar therapeutic areas as ours. This competition will reduce the number and types of patients and qualified clinical investigators available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a competitor or clinical trial sites may not allow us to conduct our clinical trial at such site if competing trials are already being conducted there.

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

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

Our preclinical studies of, and clinical trials, if any, with, any of our therapeutic candidates may fail to demonstrate adequately the safety, potency, purity and efficacy necessary for continued and timely development, regulatory approval and commercialization.

Since the number of subjects that we plan to dose in our ongoing Phase 1 clinical trial of TTX-MC138 is relatively small, the results from this clinical trial, if completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our therapeutic candidates.

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

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

There can be no assurance that we will ever be able to identify additional therapeutic opportunities for our therapeutic candidates or to develop suitable potential therapeutic candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential therapeutic candidates or other potential programs that ultimately prove to be unsuccessful. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, it could have a material adverse effect on our consolidated financial results and prospects. If we develop our therapeutic candidates, or commercialize any approved therapeutic candidates, through collaboration, licensing or other royalty arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such candidate, it could materially adversely affect our consolidated financial results and prospects.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526 or any of our other therapeutic candidates in development.

Clinical trials are required to apply for regulatory approval to market TTX-MC138 or any of our other therapeutic candidates. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. Failure can occur at any stage of the process. We do not know whether any clinical trials we begin will continue as planned, will need to be restructured or will be completed on schedule or at all. Significant clinical trial delays also could allow competitors to bring products to market before we do and could impair our ability to successfully commercialize our therapeutic candidates, any of which could materially harm our business.

There is no assurance that we will not experience additional or other delays.

We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent our ability to receive marketing approval for, or to commercialize, TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526 or any of our other therapeutic candidates in development, including the following:

- regulators, IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site, on our anticipated timelines, including as a result of failing to obtain any clearances necessary to conduct clinical trials or being subject to clinical holds that prevent continuation of such trials;

- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design;

- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, or with for-profit and not-for-profit industry organizations, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- the number of subjects required for clinical trials of any therapeutic candidates may be larger than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;

- delays and interruptions to our clinical trials could extend the duration of the trials and increase the overall costs to finish the trials as our fixed costs are not substantially reduced during delays;

- we may elect to, or regulators, IRBs, Data Safety Monitoring Boards, or DSMBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any therapeutic candidates may be greater than we anticipate;

- the supply or quality of our therapeutic candidates or other materials necessary to conduct clinical trials of our therapeutic candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and

- the FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long-term toxicology studies or may impose other requirements before permitting us to initiate a clinical trial.

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

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

As therapeutic candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, various aspects of the development program, such as manufacturing methods and the product's formulation, may be altered in an

effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. These changes carry the risk that they will not achieve their intended objectives. Any of these changes could cause our therapeutic candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our therapeutic candidates and jeopardize our ability to commercialize our therapeutic candidates and generate revenue.

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

Quality problems could delay or prevent delivery of our product candidates to clinical trials or the market.

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

We are required to comply with FDA's good clinical practice, or GCP, regulations for our clinical programs.

As it relates to the manufacturing of both our drug substance and drug product, or biological product, we are required to adhere to FDA's current good manufacturing practice, or cGMP, regulations and, if applicable, the FDA's current good tissue practice, or CGTP, for the use of human cellular and tissue products. Additionally, we must follow guidelines promulgated by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH Guidelines. The ICH Guidelines to which we are subject are ICH E6 (R2) and ICH E8 (R1), "Designing quality into clinical studies," for all tasks related to clinical programs, and ICH Q7 for the manufacture of our drug substance and drug product.

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

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

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

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

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

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

We face an inherent risk of product liability once we begin testing TTX-MC138 and any of our other therapeutic candidates in clinical trials and will face an even greater risk if we commercialize any products.

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

- inability to bring a therapeutic candidate to the market;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial subjects and inability to continue clinical trials;
- initiation of investigations by regulators;
- regulatory or IRB action resulting in a clinical trial being placed on clinical hold;
- fines, injunctions or criminal penalties;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any therapeutic candidate, if approved; and
- decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We will need to obtain insurance for clinical trials as TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526 and any of our other therapeutic candidates begin clinical development. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product

liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

If we are unable to advance our therapeutic candidates through clinical development to obtain regulatory approval and ultimately commercialize our therapeutic candidates, or we experience significant delays in doing so, our business will be materially harmed.

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

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

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

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

- disagreement with the design or implementation of clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product-candidate is safe and effective for any indication;
- we may be unable to demonstrate that a product-candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from manufacturing results, preclinical studies or clinical trials;
- the results of our clinical trials may not demonstrate the safety or efficacy required by the FDA for approval; or
- the FDA may find deficiencies in our manufacturing processes or facilities; and the FDA's approval policies or regulations may significantly change in a manner rendering our clinical data insufficient for approval.

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

Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular therapeutic candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or the labeling or other restrictions. In addition,

the FDA has the authority to require a Risk Evaluation and Mitigation Strategy, or REMS, plan as part of or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

We have received Orphan Drug Designations for TTX-MC138 and TTX-siPDL1 for pancreatic cancer, and may in the future seek Orphan Drug Designation for our current or future product candidates in other indications and for some of our other current and future therapeutic candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

As part of our business strategy, we may seek orphan drug designation for any any eligible product cndidates we develop, and we may be unsuccessful. Under the Orphan Drug Act, the FDA may grant orphan designation to a therapeutic candidate or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. There can be no assurances that we will be able to obtain orphan designations for our product candidates.

We have received two Orphan Drug Designations in the U.S. and may pursue additional Designations for other current or future therapeutic candidates in additional orphan indications in which there is a medically plausible basis for the use of these products. Even when we obtain Orphan Drug Designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek Orphan Drug Designation for other therapeutic candidates, we may never receive such designations. For example, the FDA has expressed concerns regarding the regulatory considerations for Orphan Drug Designation as applied to tissue agnostic therapies, and the FDA may interpret the Federal Food, Drug and Cosmetic Act, or FD&C Act, and regulations promulgated thereunder in a way that limits or blocks our ability to obtain Orphan Drug Designation or Orphan Drug Exclusivity, if our therapeutic candidates are approved, for our targeted indications.

Depending on what changes FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A Breakthrough Therapy designation by FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Breakthrough Therapy designation for some or all of our current and future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by FDA may also be eligible for other expedited approval programs, including Accelerated Approval.

Designation as a breakthrough therapy is within the discretion of FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for some or all of our current and future product candidates, there can be no assurance that we will receive Breakthrough Therapy designation.

A Fast Track designation by the FDA, even if granted for any of our product candidates, may not lead to faster development, regulatory review or approval, and does not increase the likelihood that our product candidates will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. Fast track designation has been granted for Seviprotimut-L (for adjuvant use in Stage IIB/IIC melanoma), and we may seek Fast Track designation for some or all of our current and future product candidates, but there is no assurance that the FDA will grant this status to any of our current or future product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for Priority Review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

We may seek an accelerated approval pathway for one or more of our current or future product candidates, including TTX-MC138, but even if granted, it may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our therapeutic candidates will receive marketing approval.

We may seek an accelerated approval pathway for one or more of our current or future product candidates, including TTX-MC138. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage over available therapies after a determination that the product candidate has an effect on a surrogate endpoint, or intermediate clinical endpoint, that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. There can be no assurance that the FDA would allow any of the product candidates we may develop to proceed on an accelerated approval pathway, and even if the FDA did allow such pathway, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all.. Moreover, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. The FDA may further withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Accordingly, even if we receive accelerated approval, any post-approval studies required to confirm and verify clinical benefit may not show such benefit, which could lead to withdrawal of any approvals we had obtained. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that therapeutic candidate. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

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

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

Disruptions at FDA and other agencies may also slow the time necessary for new therapeutic candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as FDA and the SEC, have had to furlough critical employees and stop critical activities. Should FDA determine that an inspection is necessary for approval and an inspection cannot be

completed during the review cycle due to restrictions on travel or for other reasons, and FDA does not determine that a remote interactive evaluation will be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to a pandemic and may experience delays in their regulatory activities.

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

Even if we receive regulatory approval of TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526, 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.

Any regulatory approvals that we receive for TTX-MC138, Seviprotimut-L, UIO 524, UIO 525, UIO 526, or another product-candidate may require post-marketing surveillance to monitor the safety and efficacy of the product and may require us to conduct post-approval clinical studies. The FDA may also require a REMS in order to approve our therapeutic candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our therapeutic candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our therapeutic candidates will be subject to extensive and ongoing regulatory requirements. These requirements can include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP, for any clinical trials that we conduct post-approval and applicable product tracking and tracing requirements. Compliance with ongoing and changing requirements takes substantial resources and, should we be unable to remain in compliance, our business could be materially and adversely affected.

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

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

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

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

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

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

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

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

- adverse regulatory inspection findings;
- FDA Form 483s, untitled letters, warning letters;
- voluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals;
- restrictions on, or prohibitions against, marketing our products;
- restrictions on, or prohibitions against, importation or exportation of our products;
- suspension of review or refusal to approve pending applications or supplements to approved applications;
- exclusion from participation in government-funded healthcare programs;
- exclusion from eligibility for the award of government contracts for our products;
- suspension or withdrawal of product approvals;
- product seizures;
- injunctions; and

- civil and criminal penalties and fines.

We may develop, or enter into a collaboration or partnership to develop, in vitro diagnostics, including potentially complementary diagnostics and/or companion diagnostics, for our current or future therapeutic candidates. If we, or our future collaborators, are unable to successfully develop such diagnostics, or experience significant delays in doing so, we may not realize the full commercial potential of our future therapeutic candidates.

We have little experience in the development of *in vitro* diagnostics and, as such, we may rely on future collaborators in developing appropriate *in vitro* diagnostics to pair with our current or future therapeutic candidates. We have not yet begun discussions with any potential partners with respect to the development of complementary diagnostics and/or companion diagnostics and may be unsuccessful in entering into collaborations for the development of any complementary and/or companion diagnostics for our programs and our current or future therapeutic candidates.

In vitro diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval or clearance prior to commercialization. If we, our collaborators, or any third-parties that we engage to assist us, are unable to successfully develop complementary diagnostics and/or companion diagnostics for our therapeutic candidates and any future therapeutic candidates, or experience delays in doing so:

- the development of our therapeutic candidates and any other future therapeutic candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials; and

- we may not realize the full commercial potential of our therapeutic candidates and any other future therapeutic candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify, or it takes us longer to identify, patients who are likely to benefit from therapy with our products, if approved.

If any of these events were to occur, our business would be harmed, possibly materially.

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

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

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

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistle-blower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. False

Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties. Government enforcement agencies and private whistle-blowers have investigated pharmaceutical companies for or asserted liability under the False Claims Act for a variety of alleged promotional and marketing activities, such as providing free products to customers with the expectation that the customers would bill federal programs for the products; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for "off-label" uses; and submitting inflated best price information to the Medicaid Rebate Program. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

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

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

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

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

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

Obtaining and maintaining regulatory approval for our 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.

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

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

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

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (1) changes to our manufacturing and supply arrangements; (2) additions or modifications to product labeling; (3) the recall or discontinuation of our products; (4) modifications to pricing and costs; or (5) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. See the section of this Annual Report titled "*Business—Government Regulation—Current and Future Healthcare Reform Legislation*."

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

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

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

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year that will remain in effect through 2031, unless additional congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

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

Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, consolidated financial condition, consolidated results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product and any future products or put pressure on our product pricing, which could negatively affect our business, consolidated financial condition, consolidated results of operations and prospects. These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our therapeutic candidates for which we may obtain regulatory approval or the frequency with which any such therapeutic candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved therapeutic candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

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

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

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

The costs of healthcare internationally have risen significantly over the past decade. Numerous initiatives and reform by legislators, regulators and third-party payers to curb these costs have reduced reimbursement rates. One outcome of these dynamics is that hospitals and others are consolidating into larger integrated delivery networks and group purchasing organizations in an effort to reduce administrative costs and increase purchasing power. This consolidation has resulted in greater pricing pressure on suppliers, decreased average selling prices and changes in medical practices. If we secure marketing approval for our therapeutic candidates, our

commercial success will be determined by, among other things, our ability to obtain acceptable pricing for approved products which will be subject to, among other things, the factors described above.

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

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

Risks related to commercialization

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

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

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

In the United States and in other countries, patients who are prescribed treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment.

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

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

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

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

Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug or biologic product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer price, or AMP, and Medicaid rebate amounts reported by the manufacturer. As of 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, expanded the types of entities eligible to receive

discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As the required 340B discount is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. The Centers for Medicare & Medicaid Services, or CMS, has previously and may in the future implement reductions in Medicare Part B reimbursement for 340B drugs through notice and comment rulemaking. It is unclear how such reimbursement reductions could affect covered hospitals who might purchase our products in the future, and affect the rates we may charge such facilities for our approved products.

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

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

The development and commercialization of new oncology drug products is highly competitive. We may face competition with respect to any therapeutic candidates that we seek to develop or commercialize in the future from major biotechnology and biopharmaceutical companies, specialty biotechnology and biopharmaceutical companies, and other biotechnology and biopharmaceutical companies worldwide.

Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Not only must we compete with other companies that are focused on therapeutics that treat cancer, but also any therapeutic candidates that we successfully develop and commercialize will compete with existing and new therapies that may become available in the future. Our competitors may develop more successful products similar to ours sooner than we can commercialize ours, which may negatively impact our results. Companies that we are aware of with targeted therapeutics in the treatment of various cancers include Ionis, Moderna, Alnylam, BioNTech, Dicerna, Siranomics, among others which have therapeutic candidates in various stages of preclinical and clinical developments. Arrowhead Pharmaceuticals is a clinical stage company with a pipeline of investigational RNAi therapeutics. However, we know of no other companies currently in clinical development with miRNA therapeutics targeting metastatic disease. For additional information regarding our competition, see "*Business - Competition*."

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

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

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

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

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

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

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

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

Sales of our products may involve a lengthy sales cycle.

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

Risks related to third-parties and suppliers

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

We do not have our own manufacturing facilities or personnel. We currently rely, and expect to continue to rely, primarily on third-parties for the manufacture of TTX-MC138, Seviprotimut-L, UIO 524, 525, 526 and any future therapeutic candidates that we may develop. There can be no assurance that our preclinical and clinical development product supplies will not be limited or interrupted, or that they will be of satisfactory quality or continue to be available at acceptable prices. Any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements.

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

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

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

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

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

Our dependence upon others for the manufacture of our therapeutic candidates or products may adversely affect our ability to commercialize any products that receive marketing approval on a timely and competitive basis. Thus, our current and anticipated future dependence upon others for manufacturing may adversely affect our timelines and our future profit margins which could have a material adverse effect on our consolidated financial results and the value of our stockholders investment.

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

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

We will rely especially heavily on universities, medical institutions, CROs and other third-parties for the conduct of our clinical trials. While we are obligated to ensure compliance by third-parties with clinical trial protocols and other aspects of our clinical trials, and to have mechanisms in place to monitor our clinical trials, the sites at which they are conducted, and the investigators and other personnel involved in our clinical trials, we have limited control over these entities and individuals and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Our reliance on third- parties does not relieve us of our regulatory responsibilities for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third-parties are required to comply with GCP requirements for therapeutic candidates in clinical development. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third-parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with GCP requirements.

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

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

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

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

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

Outside manufacturers may not be able to or may not comply with cGMP regulations or similar regulatory requirements outside the U.S. Our failure, or the failure of our manufacturers, to comply with applicable regulations could delay clinical development or marketing approval or result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of therapeutic candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

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

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

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

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

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

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

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

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

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

If we fail to establish and maintain strategic partnerships related to our therapeutic candidates, we will bear all of the risk and costs related to the development and commercialization of our therapeutic candidates.

This may require us to seek additional financing, hire additional employees and otherwise develop expertise which we do not have. These factors could materially and adversely affect the development or commercial success of any product-candidate for which we do not arrange a strategic partnership.

Risks related to managing our business and operations

We face risks related to health epidemics, pandemics and other widespread outbreaks of contagious disease, including a pandemic, which could significantly disrupt our operations, impact our consolidated financial results or otherwise adversely affect our business.

Significant outbreaks of contagious diseases and other adverse public health developments could have a material adverse effect on our business operations and consolidated operating results., some of which may include:

- delays or difficulties in commencing enrollment of patients in our planned clinical trials;
- the impact from potential delays, including potential difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures that are deemed non-essential, which may impact the integrity of subject data and clinical trial endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

In December 2022, we signed a two-year sublease for office and lab space in Newton, Massachusetts, which commenced February 1, 2023 and terminated January 31, 2025. We are subsequently conducting our R&D activities primarily in conjunction with Michigan State University, or MSU, with which we have a sponsored research agreement. We moved our business operations into office space in Woburn, Massachusetts, under a short-term arrangement and we rent office space in Boca Raton, Florida.

While we believe that our arrangement with MSU will be satisfactory, there is no assurance that this will be the case. Should activities at MSU be limited, or should other restrictions be imposed, our development work would be adversely affected. The extent of such adverse effects will depend on future developments which are highly uncertain and cannot be predicted. In addition, the MSU arrangement may not meet all our requirements.

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

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

As of April 3, 2026, we had 12 employees who work at locations in six states. We also utilize various outside companies and individuals under consulting or other arrangements to support our operations. As our clinical development and commercialization plans and strategies develop, and as we continue to operate as a public company, we expect to need additional human resources in areas including management, clinical and regulatory, manufacturing, research, medical, sales, marketing, financial, and other. Future growth would impose significant added responsibilities on members of management, including:

- recruiting, integrating, retaining and motivating additional employees;
- managing our development efforts effectively, including the clinical, manufacturing and quality review process for our therapeutic candidates, while complying with our contractual obligations to contractors, collaboration partners and other third-parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

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

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

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

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

Our ability to compete in the highly competitive oncology industry depends upon our ability to attract and retain highly qualified managerial, scientific and operations personnel. We are dependent on our management, scientific and medical personnel and advisors, including our CEO and Chairman, Philippe Calais, PhD; our CFO, Principal Financial Officer and director, Thomas A. Fitzgerald; our co-founder and Chief Scientific Officer, Dr. Zdravka Medarova; our co-founder and advisor, Dr. Anna Moore; our board of directors and members of our scientific and business advisory boards as well as our many consultants. The loss of the services of any of these individuals or entities, and our inability to find suitable replacements, could result in delays in product development and materially harm our business.

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

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

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

We may be exposed to significant foreign exchange risk.

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

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

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

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

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

private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our consolidated results of operations in future years.

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

Risks related to intellectual property

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

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

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

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

Further, if we encounter delays in our clinical trials, the period of time during which we could market our therapeutic candidates under patent protection would be reduced.

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

Some of the patents that we control were filed prior to March 16, 2013, and are thus based on the "first- inventor-to-invent" criterion. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for United States applications in which at least one claim is not entitled to a priority date before March 16,

2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor's disclosure.

We may be required to disclaim part or all of the term of certain patents. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim.

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

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

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

- others may be able to make or use compounds that are similar to the compositions of our therapeutic candidates but that are not covered by the claims of our patents or those of our licensors;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any licensed patents and patent applications invented or developed using U.S. government funding, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;

- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;

- the claims of our owned or licensed issued patents or patent applications, if and when issued, may not cover our therapeutic candidates;

- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third-parties;

- the inventors of our owned or licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;

- it is possible that our owned or licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;

- we have engaged in scientific collaborations in the past and expect to continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;

- we may not develop additional proprietary technologies for which we can obtain patent protection;

- it is possible that therapeutic candidates or diagnostic tests we develop may be covered by third- parties' patents or other exclusive rights; or

- the patents of others may have an adverse effect on our business.

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

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on therapeutic candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third-parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

Our commercial success depends in part on our ability to develop, manufacture, market and sell our therapeutic candidates and use our proprietary technologies without infringing the proprietary rights of third- parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

We may be exposed to, or threatened with, future litigation by third-parties having patent or other intellectual property rights alleging that our therapeutic candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third-parties, exist in the fields in which we are developing our therapeutic candidates. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our therapeutic candidates may give rise to claims of infringement of the patent rights of others.

Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third-parties may allege they have patent rights encompassing our therapeutic candidates, technologies or methods.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to

challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first inventor to file" system. The first-inventor-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, consolidated results of operations and consolidated financial condition.

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

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

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

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

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

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us.

These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third-parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third-parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing

such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third-parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, consolidated financial condition, consolidated results of operations, and prospects.

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

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

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

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

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

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

General Risk Factors

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

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

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

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

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty

preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, consolidated results of operations, consolidated financial condition, prospects and consolidated cash flows. Any failure by such third-parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Like many other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems and attempts to damage or steal our property, information or financial resources, including through malicious codes and viruses, phishing, business email compromise attacks, and attempted ransomware or other cyber-attacks. Whereas none of these instances has had a material impact on us so far, the number and complexity of these threats continue to increase over time. For example, in July 2021, we were subject to what we believe was a phishing attack. We do not believe this incident had a material impact on our business or consolidated financial condition. However, the number and complexity of these threats continue to increase. If a material breach of our information technology systems or those of our third-party service providers occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. Such a material breach could also have a material adverse effect on our business, consolidated financial condition or consolidated results of operations.

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

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

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

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

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, unintentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U.S. and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, patient support and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide

range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third- parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our consolidated results of operations.

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

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

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

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us

to change our business practices and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

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

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

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

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

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

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

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

These developments could lead to supply chain disruption, inflation, higher interest rates, and uncertainty about business continuity, which may adversely affect our business, consolidated financial condition and our consolidated results of operations. They are likely to make obtaining equity capital more difficult and more expensive.

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

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

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

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

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

In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, if we establish operations or conduct clinical trials in Europe, we will be subject to European data privacy laws, regulations and guidelines. The General Data Protection Regulation, (EU) 2016/679, or GDPR, became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the European Economic Area, or EEA. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, keeping personal information secure, having data processing agreements with third-parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping.

The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to €10 million or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to €20 million or up to 4% of our total worldwide annual turnover (i.e., revenues), whichever is greater, for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers.

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

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

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

We or any future strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. If we, our licensors or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay substantial damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. In addition, we, our licensors or any future strategic partners may choose to seek, or be required to seek, a license to technology owned by a third-party, which license may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be limited which could give our competitors access to the same technology or intellectual property rights as is licensed to us. If we fail to obtain a required license, we may be unable to effectively market certain approved products which could materially harm us. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in litigation or other proceedings relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and would divert our management's attention from operating the business. Most of our competitors would be better able to sustain the costs of complex patent litigation than us because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could materially delay our research and development efforts and significantly limit our ability to continue our operations.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to compliance activities and investor relations.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and consolidated financial condition. In addition, the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes- Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices.

Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of an initial public offering. We intend to continue to take advantage of this legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

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

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

Risks related to our Common Stock

If you purchase our securities, you may be subject to substantial dilution in the book value of your shares.

We will need to raise additional capital in the future. To the extent we raise additional capital through the issuance of equity or convertible debt securities in the future, there will be dilution to investors and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights.

In April 2026, we entered into the SEPA and expect to issue the First Convertible Note. The issuances of Common Stock pursuant to the SEPA and upon conversion of the First Convertible Note may cause immediate and substantial dilution to our existing stockholders and could cause a significant reduction in the market price of our Common Stock.

Future issuances of our Common Stock or other equity securities, whether pursuant to the SEPA or otherwise, or the perception that such sales may occur, could adversely affect the trading price of our Common Stock and impair our ability to raise capital through future offerings of shares or equity securities. We may choose to raise additional capital through the issuance of equity or convertible debt securities due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. No prediction can be made as to the effect, if any, that future sales of Common Stock or securities convertible into Common Stock, or the availability of Common Stock for future sales, will have on the trading price of our Common Stock.

There is no public market for our common stock purchase warrants.

There is no established public trading market for the common stock purchase warrants we have issued. We will not list the common stock purchase 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. Without an active market, the liquidity of our common stock purchase warrants will be limited.

Our common stock purchase warrants are speculative in nature.

Common stock purchase 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 may exercise their right to acquire the underlying common stock and pay the respective stated warrant exercise price per share.

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

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

Trading volume in shares of our common stock on the Nasdaq Capital Market has been limited. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. 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 fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price has been volatile since our initial public offering. The stock market in general, and the market for the stocks of many smaller biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations often unrelated or disproportionate to the operating performance of particular companies. We believe that this has occurred for numerous reasons including as a result, economic events and expectations, the war in the Ukraine and the current armed conflict in Israel and the Gaza Strip, with Israel having declared of war on Hamas, a U.S. designated Foreign Terrorist Organization, due to recent attacks. 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 consolidated financial results, development timelines or recommendations by securities analysts;
- variations in our consolidated 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;
- future sales of our Common Stock, debt securities convertible into equity, and conversion of our Series A Preferred Stock, Series B Preferred Stock, and Series C Preferred Stock and the Convertible Notes;
- general economic, industry and market conditions;
- potential delisting from Nasdaq; and
- the other factors described in this "Risk Factors" section.

If the market price of our common stock declines, you may not realize any return on your investment in us and further 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.

Securities sales practice requirements may limit a stockholder's ability to buy and sell our securities.

Effective June 30, 2020, the SEC implemented Regulation Best Interest requiring that "A broker, dealer, or a natural person who is an associated person of a broker or dealer, when making a recommendation of any securities transaction or investment strategy involving securities (including account recommendations) to a retail customer, shall act in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker, dealer, or natural person who is an associated person of a broker or dealer making the recommendation ahead of the interest of the retail customer." This is a significantly higher standard for broker-dealers to recommend securities to retail customers than under prior FINRA suitability rules. FINRA suitability rules still apply to institutional investors and require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending securities to their customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information, and, for retail customers, determine that the investment is in the customer's "best interest," and meets other SEC requirements. Both SEC Regulation Best Interest and FINRA's suitability requirements may make it more difficult for broker-dealers to recommend that their customers buy speculative, low-priced securities. They may affect investing in our common stock, which may have the effect of reducing the level of trading activity in our securities. As a result, fewer broker-dealers may be willing to make a market in our common stock, reducing a stockholder's ability to resell shares of our common stock.

Raising additional capital may cause dilution to our stockholders, 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, grant rights to develop and market current or future therapeutic candidates that we would otherwise prefer to develop and market ourselves, or restrict or curtail our operations.

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 clinical development of TTX-MC138. Our cash resources at December 31, 2025, are insufficient to fund our planned operations or development plans beyond approximately year end 2026. We may not be able to complete our planned Phase 2a clinical 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 consolidated 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 and our shareholders.

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.

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 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 clinical and 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 geopolitical events 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, consolidated 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, the commercialization of any therapeutic candidates, be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, or restrict or curtail operations, any of which could materially affect our business, consolidated financial condition and consolidated results of operations.

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

We are an emerging growth company, or EGC, as defined in the JOBS Act, enacted in April 2012. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an EGC for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an EGC until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering (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 consolidated 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, by 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 in 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 consolidated financial condition or consolidated 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 of 2002, or Section 404, 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 consolidated 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 preparation of our consolidated financial statements to meet the requirements of our IPO, we determined that material weakness in our internal control over financial reporting existed during the year ended December 31, 2021. Prior to our IPO in 2021, we did not design and therefore did not have an effective control environment commensurate with our current 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.

In connection with the preparation of our consolidated financial statements as of and for the years ended December 31, 2025 and 2024, we identified material weaknesses in our control over financial reporting, and determined that a small number of these material weaknesses remained unremediated from when they were first identified during the year ended December 31, 2021, in connection with the preparation of our consolidated financial statements for our IPO. While these material weaknesses did not result in a misstatement for these years, each 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 consolidated financial statements that would not have been prevented or detected.

To remediate the material weaknesses in our internal control over financial reporting and address the material weaknesses in our accounting processes, we have established more robust accounting policies and procedures and added new accounting staff support. Also, in September 2022, we engaged an independent consultant to assist us in determining what personnel are needed, in evaluating new accounting policies, and in enhancing the robustness of our reporting systems and procedures. This work is ongoing.

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:

- subject to available funding, hiring 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 consolidated 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 consolidated financial results or prevent fraud. As a result, stockholders could lose confidence in our consolidated 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 consolidated 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 consolidated financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported consolidated financial information, which could have a negative effect on the trading price of our stock.

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

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 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 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;
- a requirement that no member of our Board 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 for approval by 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 to issue preferred stock on terms determined by the Board 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 or initiate actions that are opposed by the then-current Board 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 could cause the market price of our common stock to decline.

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 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.

There is no guarantee that the Acquisition will increase stockholder value.

On October 8, 2025, we consummated the Acquisition. We cannot guarantee that the Acquisition and related transactions will not impair stockholder value or otherwise adversely affect our business. The Acquisition poses significant integration challenges between our businesses and employees which could result in management and business disruptions, any of which could harm our consolidated results of operation or business prospects and impair the value of the Acquisition to our stockholders.

The Acquisition is subject to a contractual repurchase right in certain circumstances, which could have a material adverse effect on our consolidated results of operations, consolidated financial condition, and consolidated cash flows.

In connection with the Acquisition, we agreed to enter into a Repurchase Agreement with DEFJ pursuant to which DEFJ has the right, but not the obligation, to exercise an option to acquire all of our rights in and to the membership interests of ABCJ (the "Interests") from us (the "Repurchase Option") upon the occurrence of specified events. In the event that the Repurchase Option is exercised, we will be required to sell all of the Interests in exchange for the same amount for which we initially purchased them, which could have a material adverse effect on the price of our Common Stock, our consolidated results of operations and consolidated financial condition.

We may be required to settle certain shares of Preferred Stock for cash, which could have a material adverse effect on our business and consolidated financial condition.

The Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock and Series B Non-Voting Convertible Preferred Stock, dated October 27, 2025, (the "Certificate of Designation") provides that if we fail to deliver certificates or electronic entries representing the shares of Common Stock issuable upon conversion of the Series A Non-Voting Convertible Preferred Stock (the "Series A Preferred Stock") or the Series B Non-Voting Convertible Preferred Stock (the "Series B Preferred Stock" and, together with the Series A Preferred Stock, the "Preferred Stock") to the holders of Preferred Stock in compliance with the Certificate of Designation, each such undelivered share of Common Stock may be settled for cash at the option of the holder of Preferred Stock at a price per share equal to the then-current fair value of a share of Common Stock. In addition, solely with respect to the shares of Series A Preferred Stock, upon the occurrence of the conditions set forth in the Repurchase Agreement, if we fail to consummate the repurchase if the Repurchase Option is exercised, each such undelivered share of Common Stock may be settled for cash at the option of the holder of Series A Preferred Stock at a price per share equal to the then-current fair value of a share of Common Stock. If we are required to cash settle a significant amount of Preferred Stock, we may not have sufficient liquidity to satisfy our obligations, which could have a material adverse effect on our business and consolidated financial condition.

Stockholders may not realize a benefit from the Acquisition and Investment commensurate with the ownership dilution they have experienced, and may in the future experience, in connection with the Acquisition and Investment, including the issuance of our Common Stock upon conversion of all outstanding shares of Preferred Stock issued in the Acquisition and Investment.

If we are unable to realize the full strategic and financial benefits currently anticipated from the Acquisition and Investment, stockholders will have experienced substantial dilution of their ownership interests in us without receiving commensurate benefit, or, to the extent we are able to realize only part of the strategic and financial benefits currently anticipated from the Acquisition and Investment, only receiving part of the commensurate benefit.

The failure to successfully integrate our existing business with that of Polynoma in the expected timeframe would adversely affect our future results.

Our ability to successfully integrate our and Polynoma's operations will depend, in part, on our ability to realize the anticipated benefits from the Acquisition. If we are unable to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits of the Acquisition may not be realized fully, or at all, or may take longer to realize than expected, and the value of our Common Stock may be adversely affected. In addition, the integration of our and Polynoma's respective businesses will be a time-consuming and expensive process. Proper planning and effective and timely implementation will be critical to avoid any significant disruption to our operations. It is possible that the integration process could result in the loss of key employees, the disruption of our ongoing business or the identification of inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with suppliers, distributors, creditors, lessors, clinical trial investigators or managers or to achieve the anticipated benefits of the Acquisition. Delays encountered in the integration process could have a material adverse effect on our consolidated expenses, consolidated operating results, consolidated financial condition, and the value of shares of our Common Stock.

If DEFJ were to convert a substantial majority of the Preferred Stock that it holds, we could become a "controlled company" within the meaning of the Nasdaq listing standards and, as a result, we would qualify for exemptions from certain corporate governance requirements.

As of the date hereof, DEFJ holds approximately 1,376.69 shares of Preferred Stock and 83,285 shares of Common Stock, which on a fully converted basis together equal approximately 90.8% of the voting power in us. Pursuant to the Certificate of Designation,

prior to our receipt of stockholders' approval of the conversion of the applicable series of Preferred Stock into shares of Common Stock (the "Polynoma Stockholder Approval"), in accordance with the listing rules of the Nasdaq Stock Market, we shall not issue more than an aggregate of 19.9% of the Common Stock outstanding as of October 8, 2025, in connection with the Acquisition and the Investment. In addition, DEFJ may not convert shares of Preferred Stock into shares of our Common Stock if such conversion would result in DEFJ beneficially owning more than 9.99% of the shares of our Common Stock outstanding immediately after giving effect to such conversion (the "Beneficial Ownership Limitation"). Any increase in the Beneficial Ownership Limitation may not be effective until after Polynoma Stockholder Approval and 60 days after we have received written notice from the holder of Preferred Stock that they intend to remove the Beneficial Ownership Limitation.

After Polynoma Stockholder Approval, DEFJ would have the ability, subject to the Beneficial Ownership Limitation, to convert its Preferred Stock and become the owner of more than 50% of the voting power in us, resulting in us qualifying as a "controlled company" under Nasdaq listing requirements. As the owner of more than 50% of the voting power of us, DEFJ would be able to determine all matters requiring approval by our stockholders. Furthermore, this concentration of voting power could have the effect of delaying, deterring, or preventing a change of control or other business combination that might otherwise be beneficial to our stockholders. This significant concentration of share ownership may also adversely affect the trading price of our Common Stock because investors may perceive disadvantages in owning stock in a Company that is controlled by a single stockholder.

If we were deemed to be a "controlled company," we would be exempt from certain Nasdaq corporate governance requirements, including those that would otherwise require the Board to have a majority of independent directors and require that we establish and maintain a compensation committee comprised entirely of independent directors, or otherwise ensure that the compensation of our executive officers and nominees for directors are determined or recommended to the Board by the independent members of the Board. While we do not currently intend to rely on any of these exemptions, following the conversion of Preferred Stock, the Board may decide to rely on such exemptions if we are considered a "controlled company." To the extent we rely on one or more of these exemptions, holders of our Common Stock will not have the same protections afforded to stockholders of companies that are subject to all of Nasdaq's corporate governance requirements.

Our future results will suffer if we do not effectively manage our expanded operations.

As a result of the Acquisition, we have become a more diversified company and our business has become more complex. There can be no assurance that we will effectively manage the increased complexity without experiencing operating inefficiencies or control deficiencies. Significant management time and effort are required to effectively manage our increased complexity and our failure to successfully do so could have a material adverse effect on our business, consolidated financial condition, consolidated results of operations and growth prospects. In addition, as a result of the Acquisition, our consolidated financial statements and consolidated results of operations for periods prior to October 8, 2025, may not provide meaningful guidance for assessing the prospects or potential success of our future business operations.

We expect to incur substantial expenses related to the integration of Polynoma.

We have incurred, and expect to continue to incur, substantial expenses in connection with the Acquisition and the integration of Polynoma. There are a number of processes, policies, procedures, operations, technologies and systems that must be integrated, including accounting and finance, billing, payroll, research and development, marketing and benefits. We and Polynoma have both incurred significant transaction expenses in connection with the drafting and negotiation of the Purchase Agreement and the related ancillary agreements. While we have assumed that a certain level of expenses will be incurred, there are many factors beyond our control that could affect the total amount or the timing of the integration expenses. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. These integration expenses likely will result in our taking significant charges against earnings in future periods, and the amount and timing of such charges are uncertain at present.

The Series A Preferred Stock and Series C Preferred Stock cannot be converted into Common Stock without stockholder approval. There is no guarantee these approvals will be obtained.

Under the terms of the Purchase Agreement and the Unleash Licensing Agreement, we agreed to call and hold a special meeting of stockholders to obtain, among other things, the requisite approvals for the conversion of all outstanding shares of Series A Preferred Stock and Series C Preferred Stock into shares of our Common Stock and to seek approval of a potential "change of control" under

Nasdaq Listing Rules 5110 and 5635(C), in each case as required by the Nasdaq Stock Market LLC listing rules (the "Series A Preferred Stockholder Approval"). At the special meeting of stockholders, we also plan to seek approval of the conversion of all outstanding shares of Series C Preferred Stock into shares of Common Stock (the "Series C Preferred Stockholder Approval"). While it is anticipated that we will receive the Series A Preferred Stockholder Approval and the Series C Preferred Stockholder Approval, there can be no guarantee that such approvals will be obtained. As of the date hereof, we have not sought stockholder approval of these conversions, although we intend to seek stockholder approval in the near future. If the Series A Preferred Stockholder Approval and the Series C Preferred Stockholder Approval are not obtained, persons holding Series A Preferred Stock or Series C Preferred Stock, as applicable, will continue to hold such shares until such time as the required stockholder approvals are obtained. We have agreed to seek to obtain such approvals at an annual or special stockholders meeting to be held at least every six months thereafter until such approval is obtained, which would be time-consuming and costly.

The Unleash Licensing Agreement and our attempts to develop the Unleash drug candidates may not result in material benefits to our business.

There can be no assurance that we will realize any of the benefits from the Unleash Licensing Agreement or realize such benefits within the anticipated timeframe. We believe that UIO-524, UIO-525, and UIO-526 present a compelling opportunity for us to expand our therapeutic approaches, but we will not be able to determine whether this belief is accurate until after reviewing the results of the necessary studies and clinical trials. These results may not validate our belief in the candidates' effectiveness or obtaining the results may take longer than anticipated. If development of the Unleash drug candidates is unsuccessful or delayed, our consolidated results of operations or consolidated financial condition could be negatively affected.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We understand the importance of assessing, identifying, and managing risks associated with cybersecurity threats. Certain cybersecurity processes designed to assess, identify and manage risks from cybersecurity threats have been incorporated into our operations as a part of our overall risk assessment process.

To help us defend against, detect and respond to risks from cybersecurity threats, we engage a third-party computer support firm to assist with network monitoring, cloud system monitoring, and employee cybersecurity awareness training. Training topics include how to escalate suspicious activities including phishing, viruses, spams, insider threats, suspect human behaviors or safety issues.

Since July 2021, we have no knowledge of any cybersecurity incidents which have materially affected or are reasonably likely to materially affect our Company, including our business strategy, consolidated results of operations, or consolidated financial condition. Refer to "Item 1A. Risk Factors" in this Annual Report on Form 10-K, including "Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our current or future therapeutic candidates' development programs," and "We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure," for additional discussion about cybersecurity-related risks.

Cybersecurity Governance

Cybersecurity is an important part of our risk management processes. Our Chief Financial Officer is the primary person in our company responsible for overseeing the cybersecurity risk management program. He has had oversight of our cybersecurity and risk management programs since the second half of 2021. This is not a full-time function for our Chief Financial Officer and because he is not an experienced computer professional, he relies to a large degree on our outside information technology, or IT, support firm. He is also immediately alerted of any cybersecurity breaches that occur by our third-party vendors or by others so that appropriate measures may be taken timely.

Our Board of Director's role in risk oversight is consistent with our leadership structure, with management having day-to-day responsibility for assessing and managing our risk exposure and our Board actively overseeing the management of our risks. The Board conducts its risk oversight by receiving reports from our executive officers regarding our risk identification, risk management, and risk mitigation strategies with respect to areas of potential material risk, including cybersecurity risk. The Board has delegated to the Audit Committee of the Board primary responsibility for overseeing risks from cybersecurity threats.

ITEM 2. PROPERTIES.

As of December 31, 2025, we conducted the majority of our R&D activities in conjunction with Michigan State University with which we recently entered a sponsored research agreement. We moved our business operations into office space in Woburn, Massachusetts, under a short-term rental arrangement. We maintain a "virtual office" at the address set forth on the cover page of this Annual Report. We also rent office space in Boca Raton, Florida.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. We do not know of any claims or actions pending against us or threatened, the ultimate disposition of which could have a material adverse effect on our consolidated results of operations or consolidated financial condition except claims by an investment bank that it is entitled to fees, claims which we have rigorously disputed.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock trades under the symbol "RNAZ" on the Nasdaq Capital Market and has been publicly traded since July 9, 2021. Prior to this time, there was no public market for our common stock.

Stockholders

As of April 3, 2026, we had 916,968 shares of common stock outstanding held by approximately 24 holders of record, one of which was Cede & Co., or Cede, a nominee for Depository Trust Company, or DTC. All of the shares of our common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are therefore considered to be held of record by Cede as one stockholder. The number of beneficial owners of our stock is greater than this number of record holders because it includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying cash dividends on our common stock in the foreseeable future. Except if required by contractual arrangements approved by our Board, any future determination to declare dividends will be made at the discretion of our Board and will depend on our consolidated financial condition, consolidated operating results, capital requirements, general business conditions and other factors that our Board deems relevant. In connection with the Purchase Agreement, we were obligated to issue additional shares of Series A Preferred Stock to holders of Series A Preferred Stock as a dividend on April 6, 2026.

Equity Compensation Plans

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Recent Sales of Unregistered Securities

All sales of unregistered securities during the year ended December 31, 2025, and through the filing date of this Annual Report on Form 10-K have previously been reported in our Quarterly Reports on Form 10-Q and/or Current Reports on Form 8-K.

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

Issuer Purchases of Equity Securities

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Company Overview

TransCode is an immuno-oncology and targeted cancer therapy company with a focus on treating advanced malignancy. Our lead therapeutic candidate, TTX-MC138, is focused on treating metastatic tumors that overexpress microRNA-10b, a unique, well-documented biomarker of metastasis.

Polynoma Acquisition. On October 8, 2025, we entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") with DEFJ, LLC, a Delaware limited liability company, ("DEFJ") pursuant to which we acquired 100% of the issued and outstanding membership interests of ABCJ, LLC, a Delaware limited liability company, ("ABCJ") (such transaction, the "Acquisition"). Prior to the Acquisition, ABCJ was a wholly owned subsidiary of DEFJ and an indirect wholly owned subsidiary of CK Life Sciences Int'l., (Holdings) Inc., a listed entity on the Main Board of the Hong Kong Stock Exchange ("CKLS"). In the Acquisition, we issued 1,242.0717 shares of Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share, (the "Series A Preferred Stock") to DEFJ. Each share of Series A Preferred Stock is convertible into 10,000 shares of Common Stock.

ABCJ owns 100% of the issued and outstanding membership interests of Polynoma, LLC, a Delaware limited liability company, ("Polynoma") previously headquartered in San Diego, California. Polynoma is an immuno-oncology focused biopharmaceutical company developing Seviprotimut-L, an investigational polyvalent antigen vaccine intended to reduce the risk of recurrence of cancer in patients with stage IIB and IIC melanoma who have limited options. Seviprotimut-L has been safely administered in clinical trials to more than 1,000 patients.

We intend to work on developing both TTX-MC138 and Seviprotimut-L, with the initial focus on advancing TTX-MC138 in a planned Phase 2a clinical trial. We believe there is potential to augment Seviprotimut-L's focus with TTX-MC138 by addressing micrometastases in stage IIB and IIC melanoma patients.

Concurrent with the Acquisition, we entered into an Investment Agreement (the "Investment Agreement") with DEFJ. Pursuant to the Investment Agreement, DEFJ agreed to purchase, and we agreed to issue and sell, in a private placement an aggregate of 223.7337 shares of Series B Non-Voting Convertible Preferred Stock, par value $0.0001 per share, (the "Series B Preferred Stock" and, together with the Series A Preferred Stock, the "Preferred Stock") for a price per share of $111,740, for an aggregate purchase price of approximately $25 million. The aggregate purchase price consisted of a cash subscription of $20 million paid on October 8, 2025, and a promissory note (the "Promissory Note") in the aggregate principal amount of approximately $5 million (together, the "Investment"). The Promissory Note accrued interest at a rate of 4% per annum, calculated as simple interest on a 365-day year. The principal and accrued interest were paid on December 30, 2025. Each share of Series B Preferred Stock is convertible into 10,000 shares of Common Stock.

Contingent Value Rights. Concurrent with the closing of the Acquisition, we entered into a contingent value rights agreement (the "CVR Agreement") with a rights agent (the "Rights Agent"), pursuant to which each holder of our Common Stock as of October 20, 2025, (the "Record Date") including those holders who received shares of Common Stock in connection with the Acquisition, is entitled to one contractual contingent value right (each, a "CVR") issued by us, subject to and in accordance with the terms and conditions of the CVR Agreement, for each share of Common Stock held by such holder as of 5:00 p.m. Eastern Daylight Time on the Record Date. The CVR Agreement has a term of seven years (the "Term").

Each CVR entitles the holders thereof (each a "Holder"), in the aggregate, to 50% of the Net Proceeds (as defined in the CVR Agreement) from any Upfront Payment (as defined in the CVR Agreement) or Milestone Payment (as defined in the CVR Agreement) we receive in a given calendar quarter during the Term. Distributions in respect of CVRs that become payable will be made on a quarterly basis and will be subject to a number of deductions, subject to certain exceptions or limitations, including but not limited to for certain taxes and certain out-of-pocket expenses we incur.

Under the CVR Agreement, the Rights Agent has, and Holders of at least 30% of the CVRs then-outstanding have, certain rights to audit and enforcement on behalf of all Holders. The CVRs may not be sold, assigned, transferred, pledged, encumbered or in any other manner transferred or disposed of, in whole or in part, other than as permitted pursuant to the CVR Agreement. Holders do not have the rights of stockholders by virtue of their CVR holdings and do not have the ability to vote, rights to dividends, or other interests. The CVRs also establish certain restrictions of mergers and change in control activities, as defined in the CVR Agreement.

Unleash Licensing Agreement. In March 2026, we entered into the Unleash Licensing Agreement with Unleash pursuant to which the we acquired a pre-clinical candidate program involving genetically-engineered adenoviruses to harness the immune system to fight cancer, as well as an exclusive, perpetual, irrevocable, worldwide, fully-paid up, royalty-free, sublicensable right and license to related technology.

As consideration for the Unleash Licensing Agreement, pursuant to an Equity Issuance and Registration Rights Agreement with Unleash (the "Unleash Registration Rights Agreement"), we agreed to issue 1,136,364 shares of our Series C Non-Voting Convertible Preferred Stock to Unleash. The Series C Preferred Stock is not convertible until our stockholders approve its conversion into Common Stock in accordance with the listing rules of Nasdaq (the "Unleash Stockholder Approval"). Following the Unleash Stockholder Approval, each share of Series C Preferred Stock is convertible into one share of our Common Stock.

Drug Candidates

In addition to TTX-MC138, we have a portfolio of other first-in-class therapeutic candidates designed to mobilize the immune system to recognize and destroy cancer cells. TTX-siPDL1 is an siRNA-based modulator of programmed death-ligand 1, or PD-L1. TTX-RIGA is an RNA-based agonist of the retinoic acid-inducible gene I, or RIG-I, targeting activation of innate immunity in the tumor microenvironment. TTX-siMYC is a siRNA-based inhibitor of c-MYC, a widely expressed but currently undruggable oncogene. Seviprotimut-L is a novel allogeneic, polyvalent partially purified shed antigens vaccine (alum adjuvanted) for the adjuvant treatment of Stage IIB and IIC melanoma patients 60 years and younger. Seviprotimut-L is derived from three proprietary human melanoma cell lines. Seviprotimut-L works by stimulating both humoral and cellular immune responses. It has completed Phase 2 clinical development and has been administered to approximately 1,000 patients in prior clinical trials.

In 2023, we conducted a Phase 0 clinical trial in one patient with advanced solid tumors. The intent of the Phase 0 trial was to demonstrate quantitative delivery of radiolabeled TTX-MC138 to metastatic lesions. In September 2024, we commenced a Phase I/II clinical trial with TTX-MC138 which was substantially completed by the end of 2025. Analysis of the Phase I/II clinical trial results is ongoing. We expect to commence a Phase 2a clinical trial in the first half of 2026.

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 and 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.

To customize the development of RNA therapeutics, we have developed a design engine that is modular at both the levels of the core nanoparticle and the therapeutic loading. The size, charge, and surface chemistry of the core iron oxide nanoparticle are 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 such as proteins, peptides, radionuclides, and small molecules 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 Pattern Recognition Receptors such as RIG-I. We believe the TTX 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.

Our 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.

TTX 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. We believe we are now closer to solving this challenge by means of our TTX platform.

Our TTX technology has gone through more than 20 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.

Our TTX nanocarrier is designed to be tunable to certain specifications to deliver therapeutic oligonucleotides to RNA targets in tumors and metastases without compromising the integrity of the oligonucleotide. We believe our 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 hepatocytes in the liver but not tumors and metastases.

Our TTX delivery platform is also designed to minimize early kidney and liver clearance, which we expect to translate 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. Because their iron core is magnetic and visible with magnetic resonance imaging, or MRI, they have the additional benefit of enabling quantification of the delivery of the particles to target organs. Our nanoparticles carry functional groups to provide stable links to the therapeutic oligonucleotides of interest through covalent bonds.

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, or PET. We believe the combined result of a hydrodynamically-favored distribution and a metabolically-triggered uptake will result in the enhanced ability of our nanoparticles to access genetic targets inside tumors.

Advancing new RNA therapies through a modular approach

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 radiolabeled TTX-MC138 to metastases, was made in laboratory tests using noninvasive PET-MRI. The key results of the study suggest that when injected intravenously, TTX-MC138 accumulates in metastatic lesions. These results suggest that our TTX platform delivers its therapeutic candidate as intended and support 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 100 micrograms.) The capacity to carry out microdosing PET-MRI studies in patients under an exploratory IND, or eIND, application could be important because they have the potential to support additional clinical trials we may propose for FDA consideration. The research described in this paper, published by Dr. Zdravka Medarova, our Chief Scientific Officer and scientific co-founder, and others, describes what we believe is an effective approach to assessing delivery of TTX-MC138 in metastatic cancer patients. Since the PET-MRI technique is sensitive enough to determine the concentration of radiolabeled drug candidate in the sub-picomolar range, microgram quantities of the radiolabeled drug candidate are believed to be sufficient to perform such a study in humans. We believe this capability has significant advantages in the initial phases of drug development.

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 radiolabeled TTX-MC138, when injected at a microdose, reflects its biodistribution at the level of a therapeutic dose.

These key findings informed the design of our Phase 0 microdose clinical trial with radiolabeled TTX-MC138 which we believe offered numerous potential advantages:

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

(ii) permitted measurement of the pharmacokinetics and biodistribution of TTX-MC138 not only in the metastatic lesions but in other tissues throughout the body, potentially informing Phase I/II clinical trial designs by allowing us to determine drug candidate uptake and clearance from vital organs;

(iii) supported assessment of pharmacokinetic endpoints, potentially informing dosing for clinical trials. Specifically, because of the high sensitivity and quantitative nature of PET-MRI, we obtained information suggesting what drug concentration in the metastatic lesions over time could be which we then could assess relative to the effective dose used in our preclinical studies; and

(iv) further informed clinical trial designs to potentially incorporate patient inclusion criteria in those designs.

Because of the potential benefits from a microdose Phase 0 clinical trial, and reflecting the studies described in *Cancer Nanotechnology*, our First-in-Human Phase 0 trial was designed to deliver a microdose of our therapeutic candidate. Results from the trial suggest the validity of our TTX pipeline for drug delivery generally, potentially opening-up additional relevant RNA targets that have been previously undruggable.

SBIR Awards

In April 2021, we received a Fast-Track Small Business Innovation Research award, or SBIR Award, from the National Cancer Institute that provided approximately $2.4 million to fund a two-phased research partnership between us and Massachusetts General Hospital. The program commenced in April 2021 and ended in March 2024. In the SBIR Award application, we proposed performing key translational experiments including IND-enabling and supporting imaging studies using MRI to assess delivery and target engagement of TTX-MC138 in metastatic lesions of breast cancer patients. The experiments were designed to achieve the following aims:

SBIR Phase I:

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

SBIR Phase II:

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

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

We believe that we achieved all three aims under this SBIR.

In September 2024, we received our second NIH Award (the "2024 Award") from the National Cancer Institute of the NIH. The 2024 Award is a Direct to Phase II SBIR Award to support IND-enabling and clinical trial activities in our clinical trial with TTX-MC138 over two years. The total 2024 Award is for $1,999,972 of which $1,011,207 applies to the first year and $988,765 applies to the second year.

Recent Developments

Phase I/II Clinical Trial

We commenced a Phase I/II clinical trial with TTX-MC138 in September 2024 at MD Anderson and three other clinical trial sites. This trial has been designed as a multicenter, open-label, dose-escalation and dose-expansion study in patients with advanced solid tumors. The Phase 1a stage of this trial involved administration of escalating therapeutic dose levels of our drug candidate in up to six cohorts of three patients or more per cohort. Preliminary data indicate no significant safety or dose limiting toxicities have been reported in the trial. To date, 77 doses of TTX-MC138 have been administered to 16 patients with advanced solid tumors. Three patients remain on trial. The median treatment duration of treatment is four months. Importantly, the duration of treatment for all patients ranged from two to twelve cycles indicative of tolerability and disease control. Sixteen patients showed positive pharmacodynamic effects over a wide dose range, consistent with preclinical results and TransCode's Phase 0 clinical trial. Key assessments in the clinical trial characterize the safety, pharmacokinetic, pharmacodynamic and anti-tumor activity of TTX-MC138 from which we have estimated a maximum tolerated dose, or MTD, and which suggest that the mechanism of action of TTX-MC138 is on target. The trial also is exploring the effect of TTX-MC138 on biomarker expression, which may include miR-10b expression, and miR-10b downstream targets (RNA sequencing). Clinical assessments to further evaluate TTX-MC138 include clinical laboratory exams, CT scan assessments, and response assessments per RECIST criteria. The Phase 2a stage of the trial is expected to commence in the first half of 2026.

Yorkville Financing

On April 7, 2026, we entered into a Standby Equity Purchase Agreement (the "SEPA") with YA II PN, LTD, a Cayman Islands exempt limited partnership, ("Yorkville") pursuant to which the Company has the right to sell to Yorkville up to $14 million of shares of Common Stock, subject to certain limitations and conditions set forth in the SEPA, from time to time during the term of the SEPA (the "Commitment Amount"). Sales of Common Stock to Yorkville under the SEPA, and the timing of any such sales, are at the Company's option, and the Company is under no obligation to sell any shares of Common Stock to Yorkville under the SEPA.

Upon satisfaction of the conditions to Yorkville's purchase obligations set forth in the SEPA, the Company can, at its sole discretion, direct Yorkville to purchase specified amounts of Common Stock. The purchase price per share for each Advance is set at 97% of the lowest daily VWAP during the three consecutive trading days beginning on the date upon which the Advance Notice is delivered. Actual sales of Common Stock to Yorkville under the SEPA will depend on a variety of factors including some to be determined by the Company, in its sole discretion, from time to time, which may include, among other things, market conditions, the trading price of the Common Stock and determinations by the Company as to appropriate sources of funding for the Company's business and operations.

In connection with the SEPA, and subject to the conditions set forth therein, Yorkville has also agreed to advance to the Company up to $6.0 million, less certain amounts as described below, to be paid in two tranches (each, a "Pre-Paid Advance" and, together, the "Pre-Paid Advances"), in exchange for the Company's issuance to Yorkville of convertible promissory notes (each, a "Convertible Note" and, together, the "Convertible Notes"). Pursuant to the Convertible Notes and the SEPA, Yorkville may convert all or any portion of the outstanding principal amount, accrued but unpaid interest, and other amounts outstanding under the Convertible Notes into shares of Common Stock, at any time and from time to time during the term of the Convertible Notes.

The first Pre-Paid Advance is expected to be disbursed to us the day after we file this Annual Report on Form 10-K. In exchange for the first Pre-Paid Advance, we shall issue to Yorkville a Convertible Note in the principal amount of $1.0 million (the "First

Convertible Note"), which will be sold with a purchase price discount of 5.0% (or $50,000). The First Convertible Note will be convertible into Common Stock at the lower of (i) a fixed conversion price equal to 115% of the VWAP on the day prior to the issuance of the Note and (ii) 95% of the lowest daily VWAP during the seven consecutive trading days immediately preceding the conversion date, but in no event lower than 20% of last reported trading price of our Common Stock on Nasdaq as quoted by Bloomberg (the "First Convertible Note Conversion Price") as of the trading day immediately prior to the date of the SEPA (the "Floor Price"). After accounting for the purchase price discount, we expect to receive gross proceeds of $950,000 for the First Convertible Note.

The second tranche of the Pre-Paid Advance shall be disbursed to the Company in exchange for the issuance to Yorkville of a Convertible Note in the principal amount of $5.0 million (the "Second Convertible Note"). The Second Convertible Note will be issued with a purchase price discount of 5.0% (or $250,000) and will be convertible into Common Stock at the lower of (i) a price equal to 115% of the VWAP on the day prior to the issuance of the Second Convertible Note and (ii) 95% of the lowest daily VWAP during the seven consecutive trading days immediately preceding the conversion date, but in no event lower than the Floor Price (the "Second Convertible Note Conversion Price," and together with the First Convertible Note Conversion Price, the "Conversion Price"). The Second Convertible Note will be issued on the second trading day after the later of (i) the registration statement filed pursuant to the SEPA, including any prospectus, amendments and supplements thereto, (the "Yorkville Registration Statement") first becoming effective under the Securities Act, (ii) the Company's receipt of stockholder approval to issue shares of Common Stock to Yorkville under the SEPA in excess of the Exchange Cap (defined below) and (iii) the approval by Nasdaq of the initial listing application required under Nasdaq Listing Rules 5110 and 5635(b). After accounting for the purchase price discount, the Company expects to receive gross proceeds of $4,750,000 pursuant to the Second Convertible Note.

Interest on the outstanding balances of the Convertible Notes will accrue at an annual rate of 5.0%, subject to an increase to 18% upon an event of default as described in the Convertible Notes. The maturity date of each Convertible Note will be 18 months from the date upon which the Convertible Note is issued. The applicable maturity date of each Convertible Note may be extended by the Company, at its option, for a period of six months on two occasions by providing written notice to Yorkville. On the applicable maturity date, any portion of the outstanding principal amount and accrued but unpaid interest that remains outstanding on such Convertible Note will automatically be converted at the then applicable Conversion Price, provided that if any Equity Condition (as defined in the Form of Promissory Note) is not satisfied, the applicable maturity date will be automatically extended until all Equity Conditions have been satisfied.

The sale and issuance of shares under the SEPA, including conversion of the Convertible Notes at Yorkville's option and the sale of shares of Common Stock at the option of the Company, is subject to an exchange cap limiting the total number of shares issuable to Yorkville to 183,301 (19.99% of outstanding shares of Common Stock before the effective date of the SEPA) (the "Exchange Cap"), unless the Company obtains stockholder approval to exceed the Exchange Cap (the "Yorkville Issuance Approval"). Additionally, Yorkville may not own more than 9.99% of the Company's outstanding Common Stock at any time, unless it provides written notice of its intention to increase this limit, effective after 65 days.

MGH License Amendment

Effective August 15, 2025, we and The General Hospital Corporation, d/b/a Massachusetts General Hospital, ("Licensor") further amended our 2018 License (the "Second Amendment") to revise diligence requirements and milestone payments. Pursuant to the 2018 License (the License"), we licensed the exclusive rights to certain intellectual property to support development of our therapeutic candidates. In connection with the Second Amendment, we paid the Licensor a license amendment fee of $75,000. The Second Amendment revised certain one-time milestone payments to be made by us to the Licensor for Products and Processes covered by the License as follows:

(i) a certain dollar amount within sixty (60) days following dosing of the first patient in the first Phase II clinical trial for a Therapeutic Product or Therapeutic Process covered by the License;

(ii) a certain dollar amount within sixty (60) days following dosing of the first patient in the first Phase III clinical trial for a Therapeutic Product or Therapeutic Process covered by the License; and

(iii) a certain dollar amount within sixty (60) days following the First Commercial Sale (as defined in the License) for a Therapeutic Product or Therapeutic Process covered by the License.

In addition, upon the occurrence of a Change of Control Liquidity Event (as defined in the Second Amendment), we shall pay Licensor up to a certain dollar amount.

Nasdaq Listing

On June 2, 2025, we received a letter from the Nasdaq Stock Market ("Nasdaq") notifying us that we were deemed in compliance with Nasdaq Listing Rule 5550(a)(2), requiring that a company maintain a minimum closing bid price of $1.00 per share. As a result, and subject to our remaining in compliance with Nasdaq listing requirements, our stock will continue to be listed on the Nasdaq.

Reverse Stock Split

On May 15, 2025, we effected a Reverse Stock Split pursuant to which every 28 shares of our issued and outstanding Common Stock was converted automatically into one issued and outstanding share of Common Stock. The Reverse Stock Split affected all stockholders uniformly and did not by itself alter any stockholder's percentage interest in our equity except to the extent that the Reverse Stock Split would result in a stockholder owning a fractional share. No fractional shares were issued in connection with the Reverse Stock Split; any stockholder who would have received fractional shares instead had their shares rounded up to the nearest whole number of shares.

March 2025 Equity Financing

On March 23, 2025, we entered into a Placement Agency Agreement, or the March Agreement, with ThinkEquity LLC, or the Placement Agent, pursuant to which we agreed to issue and sell, directly to various investors, in a registered direct offering (the "March Offering") an aggregate of approximately 366,072 shares, or the March Shares, of our Common Stock and approximately 366,072 Common Stock Purchase Warrants, or the March Warrants, to purchase approximately 366,072 shares of Common Stock at an aggregate offering price of $27.44 per share of Common Stock and accompanying March Warrant. As part of its compensation for acting as placement agent for the March Offering, we also agreed to issue to the Placement Agent warrants to purchase approximately 18,304 shares of Common Stock, or the Placement Agent Warrants, and together with the March Shares and the March Warrants, the March Securities. We received gross proceeds of approximately $10 million in connection with the March Offering before deducting placement agent fees and other offering expenses payable by us. The March Offering closed on March 25, 2025. The March Warrants are exercisable commencing March 25, 2025, expire on March 25, 2030, and have an exercise price equal to $24.08 per share. The Placement Agent Warrants are exercisable commencing March 25, 2025, expire on March 25, 2030, and have an exercise price equal to $29.96 per share.

Further Restructuring

In an effort to continue to manage our costs, in connection with the January 31, 2025, termination of our sublease of laboratory and office space in Newton, Massachusetts, we (i) determined to conduct our R&D activities primarily in conjunction with Michigan State University under a sponsored research agreement, (ii) terminated an additional research scientist, and (iii) relocated our business activities to short-term office rental space in Woburn, Massachusetts. In connection with our R&D activities, we also terminated one consulting scientist that we had engaged. In connection with integrating Polynoma's operations into our own, we terminated three former Polynoma employees and did not extend the lease on Polynoma's office in San Diego.

Financial Operations Overview

Following our IPO in July 2021, we expanded our R&D activities and company operations. We do not have any products approved for sale and have not generated any revenue from product sales. We may never be able to develop or commercialize a marketable product. We have limited experience with clinical trials, have not obtained any regulatory approvals to sell any products, have not manufactured a commercial-scale drug, or conducted sales and marketing activities. Through December 31, 2025, we received approximately $95.8 million of net proceeds, primarily from our IPO, other equity financings including the Investment Agreement, our SBIR Awards and from borrowings under convertible promissory notes between 2018 and 2020.

We have incurred significant operating losses since inception. Our net losses were approximately $34.7 million and $16.8 million for the years ended December 31, 2025 and 2024, respectively. At December 31, 2025, we had an accumulated deficit of

approximately $97.9 million. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates for which there is no assurance of occurrence. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- advance clinical trials with TTX-MC138;
- pursue preclinical studies and initiate other clinical trials with TTX-MC138;
- advance the development of our product candidate pipeline;
- continue to develop and expand our proprietary TTX platform to identify additional product candidates;
- support partnerships with industry and academic partners;
- obtain new intellectual property and maintain, expand and protect our intellectual property;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any;
- hire additional quality assurance, clinical, scientific, commercial and administrative personnel to increase our overall knowledge base, scientific expertise, experience and capabilities;
- acquire or license additional product candidates or technologies;
- expand our infrastructure and facilities to accommodate increased activities and personnel;
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our continued operation as a public company; and incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our business strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through sales of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we will likely need to consider additional cost reduction strategies, which may include, among others, amending, delaying, limiting, reducing, or terminating our development programs, and we may need to seek an in-court or out-of-court restructuring of our liabilities. In the event of such future restructuring activities, holders of our common stock and other securities would likely suffer a total loss of their investment.

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

At December 31, 2025, we had cash of approximately $17.8 million. We believe that these funds will be sufficient to support our operating expenses and capital expenditure requirements through approximately year end 2026. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

To finance our operations beyond that point, we will need to raise additional capital which cannot be assured. If we are unable to raise additional capital in sufficient amounts or on terms we find acceptable, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. See “Liquidity and capital resources.”

Impact of global economic and political developments and global pandemics

The development of our product candidates or our operations could be disrupted and materially adversely affected by global economic or political developments. In addition, economic uncertainty in global markets caused by political instability and conflict, such as the ongoing conflicts in Ukraine and the Middle East, and economic challenges caused by global pandemics or other public health events, may lead to market disruptions, including significant volatility in commodity prices, credit and capital market instability and supply chain interruptions. Our business, consolidated financial condition and consolidated results of operations could be materially and adversely affected by adverse events in the global economy and capital markets resulting from these global economic conditions and circumstances, particularly if such conditions and circumstances are prolonged or worsen.

Although our business has not been materially impacted by these global economic and political developments to date, it is impossible to predict the extent to which we may be impacted in the short and long term, or the ways in which our business, consolidated financial condition and consolidated results of operations could be affected by any of the foregoing or by other events which may occur in the future. Any such disruptions may also magnify the impact of other risks described herein or in our other filings with the SEC.

Components of our results of operations

Revenue

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

Operating expenses

Research and development expenses

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

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

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

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

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

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

In late 2024, we and The University of Texas M. D. Anderson Cancer Center (“MD Anderson”) agreed to amend our five-year strategic collaboration agreement in favor of MD Anderson focusing solely on participation in our Phase I/II clinical trial. This amendment relieved us from the obligation to make up to $10 million of collaboration payments. We are obligated to pay charges incurred by MD Anderson in connection with clinical trial services. In January 2023, we made an initial payment of $250,000 to MD Anderson recorded as a Prepaid Expense pending such time as payments under the collaboration became due. Initial expenses of the clinical trial have been charged against the initial payment and for the years ended December 31, 2025 and 2024, were $154,306 and $279,768, respectively.

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

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials, manufacturing activities, and other research and development;

- the requirement to establish an appropriate safety and efficacy profile in IND-enabling studies;

- the timing and terms of regulatory submissions and, if received, approvals to conduct clinical trials;
- the number of sites and patients needed to complete clinical trials, the length of time required to enroll suitable patients and complete clinical trials, and the duration of patient follow-ups;
- assessment by us and regulatory agencies of data generated in clinical trials;
- the timing, receipt and terms of marketing approvals, if any, from applicable regulatory authorities including the FDA and regulators outside the U.S.;
- the extent of any post-marketing approval commitments that may be required of us by regulatory authorities;
- establishing capabilities, or making arrangements with third-parties, to manufacture the quantities and quality of product we need to conduct pre-clinical studies, clinical trials and manufacturing validation activities in advance of any New Drug Applications that we may submit;
- development and timely delivery of clinical-grade and commercial-grade drug formulations as required for use in our clinical trials and for manufacturing validation and regulatory agency review in connection with pursuit, if any, we may undertake for commercial launch of therapeutic candidates that receive marketing approval;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- competitive developments; and
- maintaining an acceptable safety profile of our product candidates following approval, if any, of our product candidates.

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

General and administrative expenses

General and administrative expenses consist primarily of staffing costs comprising mainly salaries, benefits, and share-based compensation expense for personnel serving in executive, finance, and other business functions; professional fees for legal, patent, consulting, investor and public relations, accounting, tax and audit services; insurance costs, especially directors and officers liability insurance; corporate and office expenses, including facilities costs; and information technology costs.

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

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

Other income (expense)

Interest expense

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

Interest income

Interest income consists primarily of income earned on our cash balances. Our interest income has not been significant.

Grant income

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

Results of operations

The following table summarizes the approximate amounts of our consolidated results of operations for the periods indicated:

	Year Ended December 31,		
	2025	2024	Change
		(in thousands)	
Operating Expenses			
Research and development	$ 13,422	$ 9,706	$ 3,716
General and administrative			
General and administrative expenses	5,771	5,954	(183)
Acquisition-related transaction costs	8,787	—	8,787
Total general and administrative	14,558	5,954	8,604
Total operating expenses	27,980	15,660	12,320
Operating loss	(27,980)	(15,660)	(12,320)
Other income (expense)			
Change in fair value of warrant liability	(9,277)	(939)	(8,338)
Change in fair value of contigent consideration	1,584	—	1,584
Warrant Issuance Costs	—	(597)	597
Grant income	1,278	524	754
Gain on sale of equipment	—	1	(1)
Currency exchange gain (loss)	(112)	(57)	(55)
Interest income	79	1	78
Interest expense	(7)	(27)	20
Total other income (expense)	(6,455)	(1,094)	(5,361)
Loss before income taxes	(34,435)	(16,754)	(17,681)
Deferred income tax provision	(226)	—	(226)
Net Loss	(34,661)	(16,754)	(17,907)
Deemed dividend arising from warrant modification	—	(31)	31
Accrual of paid-in-kind dividends on Series A Non-Voting Convertible Preferred Stock	(1,610)	—	(1,610)
Net loss attributable to common stockholders	$ (36,271)	$ (16,785)	$ (19,486)

Comparison of the years ended December 31, 2025 and 2024

Research and development expenses

Research and development, or R&D, expenses increased $3,716 thousand in 2025 compared to 2024. The increase reflects primarily increases in clinical trial spending, costs of production of drug used in the clinical trial, and intellectual property expenses offset in part by reductions in certain preclinical testing and reduced lab facilities costs.

General and administrative expenses

General and administrative expenses increased $8,604 thousand in 2025 compared to 2024. The increase reflects primarily increased fees for professional services, primarily financial advisory, legal and accounting services related to the Acquisition, and increased compensation costs, offset in part by decreased share-based compensation expense, spending for directors and officers liability insurance, investor relations services, and facilities expenses. Our transaction costs in connection with the Acquisition were approximately $8.8 million. These costs include direct expenses as well as integration-related professional fees and other incremental costs directly associated with the Acquisition. Transaction costs were expensed as incurred and are included in General and Administration expenses in our consolidated statement of operations.

Change in fair value of warrant liability

The change in fair value of warrant liability expense was $8,338 thousand greater in 2025 compared to 2024, resulting primarily from a higher share price at December 31, 2025, and exercises of Series D warrants in the first quarter of 2025.

Grant income

Grant income increased $754 thousand in 2025 compared to 2024. Prior to September 2024, grant income was recognized under an NIH grant awarded in April 2021 to fund certain costs to advance our lead therapeutic candidate into clinical trials. The April 2021 award ended in March 2024. We were awarded a second NIH grant in September 2024. Grant income in 2025 is related to the 2024 Award.

Change in fair value of contingent consideration

The change in fair value of contingent consideration was a $1,584 thousand gain. Contingent consideration arose in connection with the Acquisition; there was no contingent consideration in 2024.

Warrant issuance costs

Issuance costs for warrants issued in connection with our December 2, 2024, Private Investment in Public Equity, or PIPE, were $597 thousand in 2024. There was no corresponding expense in 2025.

Currency exchange gain (loss)

Loss on currency exchange was $55 thousand greater in 2025 than in 2024, reflecting changes in exchange rates on billings in Euros from certain vendors.

Interest income

Interest income was $79 thousand in 2025 compared to $1 thousand in 2024 reflecting earnings on higher cash balances from equity financings in 2025.

Interest expense

Interest expense was $7 thousand in 2025 compared to $27 thousand in 2024 primarily reflecting the absence of imputed interest on right-of-use assets.

Cash flows

The following table summarizes the approximate amounts of consolidated our cash flows for the periods indicated:

	Years ended December 31,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (19,516)	$ (13,336)
Net cash used in investing activities	(4)	(22)
Net cash provided by financing activities	31,523	16,401
Net change in cash	$ 12,003	$ 3,043

Comparison of the years ended December 31, 2025 and 2024

Operating activities

During 2025, we used cash of $19,516 thousand in operating activities compared to $13,336 thousand in 2024. Cash used in operating activities in 2025 primarily reflected our net loss of $34,661 thousand offset primarily by a $9,277 thousand non-cash change in fair value of warrant liability, $6,837 thousand of non-cash transaction costs incurred in connection with the Acquisition, a $1,584 non-cash change in fair value of contingent consideration, and a $485 thousand non-cash charge for share-based compensation expense, offset in part by $477 thousand in prepaid expenses and $952 thousand in grants receivable.

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

Investing activities

During 2025, we used cash of $4 thousand in investing activities compared to $22 thousand used in 2024, reflecting primarily purchases of laboratory and computer equipment.

Financing activities

During 2025, we obtained cash of $31,523 thousand (net) from sales of equity securities. During 2024, we obtained cash of $16,401 thousand (net) from sales of equity securities.

Liquidity and capital resources

Sources of liquidity

Since inception, we have not generated any revenue from product sales or any other sources, and we have incurred significant consolidated operating losses and negative consolidated cash flows from operations. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if ever. We have funded our operations to date primarily with proceeds from our IPO and other equity financings, SBIR Awards, and funds from borrowings under convertible promissory notes. Through December 31, 2025, we had received net cash proceeds of approximately $95.8 million from these sources.

At December 31, 2025, we had cash of approximately $17.8 million.

On April 7, 2026, we entered into the SEPA with Yorkville. Pursuant to the SEPA, in exchange for Convertible Notes in the aggregate amount of $6.0 million, Yorkville agreed to advance to us 95% of the face amount of the Convertible Notes for gross proceeds of $5.7 million. The Convertible Notes may be repaid in cash or converted into shares of Common Stock. The Convertible Notes will accrue interest at an annual rate of 5% subject to an increase upon the occurrence and continuance of events of default as described in the Convertible Notes. The outstanding balance of the Convertible Notes, plus any accrued but unpaid interest, is due and payable on the 18-month anniversary of the closing date of such Convertible Note, unless otherwise agreed by the parties.

In connection with the SEPA, we have the right to sell to Yorkville up to $14.0 million of shares of our Common Stock, subject to certain limitations and conditions set forth in the SEPA. Sales of shares of Common Stock to Yorkville and the timing of any such sales, if we elect to sell shares of Common Stock to Yorkville at a future date, are at our option, and we are under no obligation to sell any shares of Common Stock to Yorkville. As consideration for Yorkville's commitment under the SEPA, we agreed to pay to Yorkville a commitment fee equal to 2.0% of the Commitment Amount, or $280,000, which may be paid in cash or shares of Common Stock based on the price per share equal to the VWAP of the Common Stock on the trading day immediately prior to the effective date of the SEPA. As of the date of this Annual Report on Form 10-K, no shares had been sold under the SEPA.

Future requirements

We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we advance preclinical activities and pursue additional clinical trials of TTX-MC138. We expect to incur additional costs associated with operating as a public company, including significant legal, accounting, tax, investor relations and other expenses.

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

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

We believe that our cash of approximately $17.8 million at December 31, 2025, will be sufficient to fund our operating expense and capital expenditure requirements through approximately year end 2026. We have based this estimate on assumptions that may prove wrong, and we could utilize our available capital resources sooner than we expect. Changed circumstances may also result in the depletion of our capital resources more rapidly than we currently anticipate. We anticipate that we will require additional capital for additional research, development, and clinical trial costs as we seek regulatory approval of our product candidates, for operations, and for licenses or acquisitions of other product candidates we may choose to pursue. If we receive regulatory approval for TTX-MC138 or other product candidates we may develop, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, all of which will vary depending on where and how we choose to commercialize approved product candidates.

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

- the scope, progress, outcome and costs of conducting preclinical development activities, clinical trials, and other research and development;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs, timing and requirements to manufacture our product candidates for our preclinical development efforts and our clinical trials;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade product meeting quality and regulatory requirements and building inventory of such product to support commercial activities;

- the ability to receive non-dilutive funding, including grants from governments, organizations and foundations;
- the revenue, if any, received from commercial sales of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining, expanding and enforcing our intellectual property rights, and defending intellectual property-related claims;
- the terms of any industry collaborations we may be able to establish;
- the extent to which we acquire or license other product candidates and technologies; and
- the efficiency with which we operate our business.

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

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

If we are unable to raise additional funds when needed, we will likely need to consider additional cost reduction strategies, which may include, among others, amending, delaying, limiting, reducing, or terminating our development programs, and we may need to seek an in-court or out-of-court restructuring of our liabilities. In the event of such future restructuring activities, holders of our common stock and other securities will likely suffer a total loss of their investment.

Contractual obligations and commitments

At December 31, 2025, we had no future minimum lease payments under non-cancelable operating lease commitments. From time to time, we enter into contracts in the normal course of business with CROs, collaborators, CMOs and other third-parties for the manufacture of our product candidates, to support clinical trials and preclinical research studies and testing, and for other purposes. Any payments due upon completion or cancellation of these contracts generally consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation although some agreements provide for termination fees or payments for the balance of the term of the agreement.

Collaboration obligations

On July 29, 2022, we signed a five-year strategic collaboration agreement with The University of Texas M. D. Anderson Cancer Center (“MD Anderson”). Under the collaboration, we anticipated making certain expenditures with respect to Phase I and Phase II clinical trials in part through MD Anderson as a clinical site. MD Anderson was also expected to provide preclinical work under the collaboration. The details of clinical and preclinical work were to be mutually agreed by the parties prior to commencing work. We had agreed to fund up to $10 million over the term of the collaboration. In January 2023, we made an initial payment of $250,000 to MD Anderson recorded as a Prepaid Expense pending such time as payments under the collaboration became due. As a result of changes at MD Anderson and the Company, we and MD Anderson agreed to amend the collaboration to continue our Phase 1a clinical trial at MD Anderson. Initial expenses of the clinical trial were charged against the initial payment made to MD Anderson. For the years 2025 and 2024, MD Anderson expenses were $154,306 and $279,768, respectively.

Critical accounting policies and significant judgments and estimates

We have based our management's discussion and analysis of consolidated financial condition and consolidated results of operations on our consolidated financial statements. Our consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses and the disclosure of contingent assets and liabilities at the dates of the consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for our judgments about the carrying values of assets and liabilities that are not readily apparent from other sources including contingent consideration. We evaluate estimates and assumptions on an ongoing basis. Our actual consolidated results may differ from amounts derived from these estimates or from amounts obtained under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our financial statements for the year ended December 31, 2025, elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Indefinite-lived intangible assets

Indefinite-lived intangible assets consist of In-Process Research and Development ("IPR&D"). The fair values of IPR&D project assets acquired in business combinations are capitalized. We generally utilize the Multi-Period Excess Earning Method to determine the estimated fair value of the IPR&D assets acquired in a business combination. The projections used in this valuation approach are based on many factors, such as relevant market size, the estimated probability of regulatory success rates, anticipated patent protection, expected pricing, expected treated population, and estimated payments (e.g., royalties). The estimated future net cash flows are then discounted to the present value using a discount rate that we believe is appropriate. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate.

Intangible assets with indefinite lives, including IPR&D, are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset's fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. We consider many factors in evaluating whether the value of our intangible assets with indefinite lives may not be recoverable, including, but not limited to, expected growth rates, the cost of equity and debt capital, general economic conditions, outlook and market performance of our industry and recent and forecasted financial performance.

Redeemable and convertible preferred stock

The Company applies ASC 480 when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within our control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' (deficit) equity.

Research and development expenses

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

We rely to a significant extent on third-parties to conduct preclinical studies, manufacture drug substance and drug products, provide materials, conduct analytical testing and to provide clinical trial services, including trial conduct, data management, statistical analysis, medical and safety monitoring, and electronic compilation. At the end of each reporting period, we compare payments made to each service provider and clinical trial site to the estimated progress towards completion of the related project. Factors that we

consider in preparing these estimates include materials delivered or services provided, milestones achieved, the number of patients enrolled in studies, and other criteria related to the efforts of these vendors. These estimates are subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, we record net prepaid or accrued expenses related to these costs.

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

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

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

Share-based compensation

We measure the expense of share-based awards granted to employees, directors and others based on the fair value of the underlying award on the date of the grant. We recognize the corresponding compensation expense of those awards over the requisite service period, generally the vesting period of the respective award.

Through the date of these consolidated financial statements, we had issued restricted stock and stock options, each with service-based vesting conditions, and recorded share-based compensation expense resulting from those awards as vesting occurred. All shares of restricted stock have vested and there is no further compensation expense to be recorded in connection with restricted stock. We would apply the graded-vesting method to all share-based awards with performance-based vesting conditions or to awards with both service-based and performance-based vesting conditions.

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

Warrant accounting

We account for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrants' specific terms and applicable authoritative guidance in ASC 480, "Distinguishing Liabilities from Equity" ("ASC 480"), and ASC 815 "Derivatives and Hedging" ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to our own ordinary shares and whether warrant

holders could potentially require "net cash settlement" in a circumstance outside of our control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end-date while the warrants are outstanding.

For issued or modified warrants that meet all the criteria for equity classification, the warrants are required to be recorded as a component of equity at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as liabilities at their initial fair value on the date of issuance, and at their fair value on each balance sheet date thereafter. Changes in the estimated fair value of warrants classified as liabilities are recognized as a non-cash gain or loss on our statements of operations.

Warrants we issued upon our financings in January and July 2024 and in March 2025 met the criteria for equity classification under ASC 815 and were classified as equity. Warrants we issued upon a financing that closed December 2, 2024, did not meet the criteria for equity classification under ASC 815 and were classified as liabilities. Warrants issued upon our financings in 2023 met the criteria for equity classification under ASC 815 and were classified as equity.

Contingent Consideration

In connection with the Acquisition, the Company agreed to make up to $95,000,000 in contingent milestone payments (each, a "Milestone Payment" and collectively, the "Milestone Payments") (the "Acquisition Obligation") to DEFJ upon the achievement within ten (10) years of the date of the MIPA of the following milestone events (each, a "Milestone Event") upon the first achievement by or on behalf of the Company (including any licensee or assignee of rights to commercialize the Seller Lead Candidate as defined in the MIPA) of the corresponding Milestone Event as follows: (i) a milestone payment of five million U.S. dollars ($5,000,000) upon the first dosing of the Seller Lead Candidate in a patient in a United States Phase 3 Clinical Study; (ii) a milestone payment of ten million U.S. dollars ($10,000,000) upon the achievement of the applicable primary endpoint in a United States Phase 3 Clinical Study of the Seller Lead Candidate; (iii) a milestone payment of twenty million U.S. dollars ($20,000,000) upon the first submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for the Seller Lead Candidate; and (iv) a milestone payment of sixty million U.S. dollars ($60,000,000) upon the first approval by the FDA of a BLA for the Seller Lead Candidate.

The estimated fair value of the Acquisition Obligation on the Effective Date and at December 31, 2025, was approximately $7.9 million and $6.4 million, respectively.

Factors that may affect future results

You should refer to "Risk Factors" elsewhere in this Annual Report on Form 10-K for a discussion of important factors that may affect our future results.

Off-balance sheet arrangements

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

Recently issued accounting pronouncements

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

Internal control over financial reporting

We previously determined that material weaknesses in our internal control over financial reporting existed prior to our IPO. See "Risk Factors" under the caption, "*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 consolidated financial*

condition or consolidated results of operations, which may adversely affect our business." We subsequently retained an independent consulting firm to assist us in improving our control systems and procedures, and have implemented new software systems designed to enhance our ability to process financial transaction information. There is no assurance that any controls we implement will prevent fraud or enable accurate or timely financial reporting. In assessing our financial controls and procedures as described in "Item 9A. Controls and Procedures," our management determined that our internal control resulted in a material weakness as of December 31, 2025, related to certain transactions arising from the Acquisition. Notwithstanding this material weakness, management believes that all significant and unusual transactions have been appropriately recorded and that our consolidated financial statements for the year ended December 31, 2025, are fairly presented in all material respects in accordance with U.S. GAAP.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the JOBS Act. We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

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

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates plus the aggregate amount of gross proceeds to us as a result of our initial public offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We will continue to be a smaller reporting company until either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies.

Information Technology Risks

Our data and computer systems are subject to threats from malicious software codes and viruses, phishing, ransomware, business email compromise attacks, or other cyber-attacks. In July 2021, we were subject to what we believe was a phishing attack. We do not believe this incident had a material impact on our business or consolidated financial condition. However, the number and complexity of these threats continue to increase. See "Risk Factors" under the caption, "*We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure*." We have taken and continue to take steps to mitigate the risk of cyberattacks including enhancing email screening, engaging with a computer support firm to provide forensics and training services, among other services, and enhancing security protocols for vendor payments. We intend to take additional steps to continue to enhance cybersecurity defenses. Despite steps we have taken or may take in the future, there is no assurance that we will not suffer material and adverse consequences as a result of cyberattacks or other computer-based activities. In addition, there is no assurance that any steps we may take will be effective or prevent material adverse effects on our consolidated financial condition or consolidated results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest rate risk

We are exposed to market risk related to changes in interest rates. At December 31, 2025 and 2024, our cash was held in checking and savings accounts at major U.S. banks. Our primary exposure to market risk is interest income sensitivity, which is affected by

changes in the general level of U.S. interest rates. However, because of the short-term nature of our holdings, an immediate 10% change in the interest rate would not materially affect the fair market value of our investments or our consolidated financial position or consolidated results of operations.

At December 31, 2025 and 2024, we had no debt outstanding other than liabilities related to the right-of-use asset from our sublease in Newton, Massachusetts. We currently, therefore, are not subject to interest rate risk related to debt.

Foreign currency exchange risk

Our primary exposure to market risk is foreign exchange rate sensitivity to the Euro, the currency for certain of our major purchases. Foreign currency transaction gains or losses, if any, are recorded as a component of other income (expense) in our consolidated statements of operations. For the year ended December 31, 2025, we recognized a loss on foreign currency transactions of approximately $112 thousand. For the year ended December 31, 2024, we recognized a loss on foreign currency transactions of approximately $57 thousand. An immediate 5% change in the Euro exchange rate would not have a material effect on our consolidated results of operations.

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

ITEM 8. FINANCIAL CONSOLIDATED STATEMENTS AND SUPPLEMENTARY DATA.

The consolidated financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those consolidated financial statements is found in Index to the consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, as incorporated into Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K, by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

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

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

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a–15(f) or 15d-15(f). Our internal control system was designed to provide reasonable assurance to our management and our Board regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Our management, with the participation of our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, our management used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013 (COSO criteria). Based on this assessment, management concluded that, due to the material weakness referred to in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, included elsewhere in this Annual Report on Form 10-K, our internal control over financial reporting was not effective and resulted in a material weakness as of December 31, 2025, related to certain transactions arising from the Acquisition. Notwithstanding this material weakness, management believes that all significant and unusual transactions have been appropriately recorded and that our consolidated financial statements for the year ended December 31, 2025, are fairly presented in all material respects in accordance with U.S. GAAP. The small size of our finance and accounting staff requires us to rely on outside parties for certain accounting analyses such as for non-routine transactions. This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Continuing Remediation Efforts

To remediate the material weakness in our internal control over financial reporting and address the material weakness in our accounting processes, we previously implemented steps to address internal control deficiencies such as implementing more robust accounting policies and procedures, implementing new accounting software, and, most particularly, hiring of or engaging additional finance and accounting personnel including consultants and other third-party resources with requisite experience and technical accounting expertise. We also engaged an independent consulting firm to assist us in determining what personnel are needed, evaluating and improving our accounting processes, and in evaluating new accounting policies.

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

weakness we identified or avoid potential future material weaknesses. Our management will continue to monitor and evaluate the effectiveness of our internal controls and procedures over financial reporting on an ongoing basis and is committed to taking further action and implementing additional enhancements or improvements, as necessary.

Changes in Internal Control over Financial Reporting

Other than the remediation measures taken to date as described above, there were no material changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the year ended December 31, 2025, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. However, we are in the process of integrating ABCJ, LLC into our system of internal control over financial reporting which may result in future changes to our internal control environment.

ITEM 9B. OTHER INFORMATION.

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this Item 10 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission with respect to our 2026 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this Item 12 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this Item 13 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

Our independent public accounting firm is WithumSmith+Brown, PC, East Brunswick, New Jersey, PCAOB Auditor ID: 100.

The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND CONSOLIDATED FINANCIAL STATEMENT SCHEDULES.

(1) For a list of the consolidated financial statements included herein, see Table of Contents on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Consolidated financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The Exhibit Index is incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

EXHIBIT INDEX

2.1+	Membership Interest Purchase Agreement dated October 8, 2025, relating to ABCJ, LLC by and between TransCode Therapeutics, Inc. and DEFJ, LLC. (Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on October 8, 2025).
3.1	Amended and Restated Certificate of Incorporation of TransCode Therapeutics, Inc. (Incorporated by reference to Exhibit 3.3 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on April 8, 2021 (File No. 333-253599)).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of TransCode Therapeutics, Inc. (Incorporated by reference to the Registrant's Form 10-K for the year ended December 31, 2023, filed on April 1, 2024).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of TransCode Therapeutics, Inc. (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on January 16, 2024).
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of TransCode Therapeutics, Inc. (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on November 29, 2024).
3.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation of TransCode Therapeutics Inc. (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on May 5, 2025).
3.6	Amended and Restated Bylaws of TransCode Therapeutics, Inc. (Incorporated by reference to Exhibit 3.5 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on April 8, 2021 (File No. 333-253599)).
3.7	Amendment No. 1 to the Amended and Restated Bylaws of TransCode Therapeutics, Inc., effective as of December 8, 2023 (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 8, 2023).
3.8	Amended and Restated Certificate of Designation of Series A Non-Voting Convertible Preferred Stock and Series B Non-Voting Convertible Preferred Stock of TransCode Therapeutics, Inc., dated October 27, 2025 (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on October 27, 2025).

3.9	Certificate of Designation of Series C Non-Voting Convertible Preferred Stock of TransCode Therapeutics, Inc., dated March 2, 2026 (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on March 3, 2026).
4.1	Description of Securities (Incorporated by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021, filed on March 31, 2022).
4.2	Form of Representative Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599)).
4.3	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on February 17, 2023).
4.4	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on June 6, 2023 (File No. 333-272082)).
4.5	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.3 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on June 5, 2023 (File No. 333-272082)).
4.6	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.4 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on June 5, 2023 (File No. 333-272082)).
4.7	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on September 25, 2023 (File No. 333-274251)).
4.8	Form of Underwriter's Warrant (Incorporated by reference to Exhibit 4.3 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on September 25, 2023 (File No. 333-274251)).
4.9	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on December 4, 2023).
4.10	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 filed with the SEC on January 17, 2024).
4.11	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 filed with the SEC on January 18, 2024).
4.12	Form of Placement Agent's Warrant (Incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 filed with the SEC on January 17, 2024).
4.13	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 24, 2024).
4.14	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 2, 2024).
4.15	Form of Series C Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 2, 2024).
4.16	Form of Series D Warrant (Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed with the SEC on December 2, 2024).
4.17	Form of Common Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 25, 2025).

4.18	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on March 25, 2025).
4.19+	Registration Rights Agreement dated October 8, 2025, by and between TransCode Therapeutics, Inc. and DEFJ, LLC (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on October 8, 2025).
4.20	Form of Convertible Promissory Notes issued to YA II PN, Ltd. (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 7, 2026).
4.21	Registration Rights Agreement, dated as of April 6, 2026, by and between TransCode Therapeutics, Inc. and YA II PN, Ltd. (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on April 7, 2026).
4.22	Equity Issuance and Registration Rights Agreement, dated as of March 2, 2026, by and between TransCode Therapeutics, Inc. and Unleash Immuno Oncolytics, Inc.
10.1#	2020 Stock Option and Incentive Plan and form of award agreements thereunder (Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, filed on February 26, 2021 (File No. 333-253599).
10.2#	2021 Stock Option and Incentive Plan and form of award agreements thereunder (Incorporated by reference to Exhibit 10.2 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599).
10.3#	Amendment No. 1 to 2021 Stock Option and Incentive Plan (Incorporated by reference to Appendix A to the Registrant's Amended Proxy Statement pursuant to Schedule 14A of the Securities Exchange Act of 1934, filed on May 20, 2024 (File No. 001-40363)).
10.4#	Amendment No. 2 to 2021 Stock Option and Incentive Plan (Incorporated by reference to Appendix A to the Registrant's Proxy Statement pursuant to Schedule 14A of the Securities Exchange Act of 1934, filed on July 15, 2025 (File No. 001-40363)).
10.5#	Senior Executive Cash Incentive Bonus Plan (Incorporated by reference to Exhibit 10.3 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599).
10.6#	Form of Indemnification Agreement between the Registrant and each of its executive officers (Incorporated by reference to Exhibit 10.4 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599).
10.7#	Form of Indemnification Agreement between the Registrant and each of its directors (Incorporated by reference to Exhibit 10.5 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599)).
10.8†	Exclusive Patent License Agreement by and between TransCode Therapeutics, Inc. and The General Hospital Corporation, d/b/a Massachusetts General Hospital, dated as of October 26, 2018 (Incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, filed on February 26, 2021 (File No. 333-253599)).
10.9†	First Amendment to Exclusive Patent License Agreement by and between TransCode Therapeutics, Inc. and The General Hospital Corporation, d/b/a Massachusetts General Hospital, dated as of October 30, 2020 (Incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, filed on February 26, 2021 (File No. 333-253599)).

10.10†	Second Amendment to Exclusive Patent License Agreement by and between TransCode Therapeutics, Inc. and The General Hospital Corporation, d/b/a Massachusetts General Hospital, dated as of September 30, 2025 (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on November 14, 2025).
10.11#	2021 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, filed on March 24, 2021 (File No. 333-253599)).
10.12#	Employment Agreement, dated as of March 24, 2021, by and Between TransCode Therapeutics, Inc. and Thomas A. Fitzgerald (Incorporated by reference to Exhibit 10.11 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on April 8, 2021 (File No. 333-253599)).
10.13#	Letter Agreement, dated as of March 24, 2021, by and Between TransCode Therapeutics, Inc. and Thomas A. Fitzgerald (Incorporated by reference to Exhibit 10.12 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1, filed on April 8, 2021 (File No. 333-253599)).
10.14	Common Stock Purchase Agreement, dated April 13, 2023, by and between TransCode Therapeutics,Inc. and White Lion Capital LLC (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 14, 2023).
10.15	Placement Agency Agreement (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 25, 2025).
10.16+	Investment Agreement dated October 8, 2025, by and between TransCode Therapeutics, Inc. and DEFJ, LLC (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A filed on October 8, 2025).
10.17	Repurchase Agreement dated October 8, 2025, by and between TransCode Therapeutics, Inc. and DEFJ, LLC (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on October 8, 2025).
10.18	Contingent Value Rights Agreement dated as of October 8, 2025, by and between TransCode Therapeutics, Inc. and Vstock Transfer, LLC (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A filed on October 17, 2025).
10.19	Employment Agreement with Philippe Calais, dated as of October 8, 2025 (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed on November 14, 2025).
10.20	Standby Equity Purchase Agreement, dated as of April 6, 2026, by and between TransCode Therapeutics, Inc. and YA II PN, Ltd. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 7, 2026).
19.1	Insider Trading Policy dated December 24, 2024 (Incorporated by reference to the Registrant's Form 10-K for the year ended December 31, 2024, filed on April 15, 2025).
23.1*	Consent of WithumSmith+Brown, PC.
24.1*	Power of Attorney (included on signature page).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Compensation Recovery Policy (Incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on April 15, 2025).
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase
104*	Cover Page Interactive Data File (formatted in Inline XBRL and included in Exhibit 101)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

† Portions of this exhibit (indicated by asterisks) were omitted in accordance with the rules of the Securities and Exchange Commission.

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

+ Certain annexes, schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: April 15, 2026

TRANSCODE THERAPEUTICS, INC.
/s/ Philippe P. Calais
Philippe P. Calais
Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY AND SIGNATURES

Each individual whose signature appears below hereby constitutes and appoints Thomas A. Fitzgerald, MBA as such person's true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file or cause to be filed the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K and Power of Attorney has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

NAME	TITLE	DATE
/s/ Philippe P. Calais Philippe P. Calais, PhD	*Director, Chairman and Chief Executive Officer (Principal Executive Officer)*	April 15, 2026
/s/ Thomas A. Fitzgerald Thomas A. Fitzgerald, MBA	*Director and Chief Financial Officer (Principal Financial and Accounting Officer)*	April 15, 2026
/s/ Elizabeth Czerepak Elizabeth Czerepak	*Director*	April 15, 2026
/s/ Erik Manting Erik Manting, PhD	*Director*	April 15, 2026
/s/ Magda Marquet Magda Marquet, PhD	*Director*	April 15, 2026
/s/ Jack Stover Jack Stover	*Director*	April 15, 2026

TRANSCODE THERAPEUTICS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of
TransCode Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of TransCode Therapeutics, Inc. (the "Company"), as of December 31, 2025 and 2024, and the related consolidated statements of operations, changes in Series A non-voting convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, has experienced cash used from operations, and has an accumulated deficit, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2020.

East Brunswick, New Jersey
April 15, 2026
PCAOB ID Number 100

TRANSCODE THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash	$ 17,813,521	$ 5,811,064
Grant receivable	952,460	—
Reimbursement right	2,297,806	—
Due from related party	638	—
Prepaid expenses and other current assets	919,440	1,282,274
Total current assets	21,983,865	7,093,338
Property and equipment, net of depreciation	370,681	51,574
Goodwill	25,744,143	—
Intangible assets	114,300,000	—
Right-of-use asset, net of amortization	—	37,731
Security deposit	—	111,856
Total assets	$ 162,398,689	$ 7,294,499
Liabilities, Series A Non-Voting Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,494,220	$ 2,708,137
Deferred grant income	—	25,408
Short-term lease liability	—	38,291
Total current liabilities	3,494,220	2,771,836
Long-term liabilities:		
Warrant liability - Series C	434,399	517,871
Warrant liability - Series D	—	6,023,526
Contingent consideration	6,364,000	—
Deferred tax liability	226,068	—
Long-term liabilities	7,024,467	6,541,397
Total liabilities	10,518,687	9,313,233
Commitments and contingencies		
Series A Non-Voting Convertible Preferred Stock – $0.0001 par value; 1,242.0718 shares and -0- shares authorized at December 31, 2025 and 2024, respectively; 1,212.1822 shares and -0- shares issued and outstanding at December 31, 2025, and 2024, respectively	141,544,536	—
Stockholders' equity (deficit):		
Series B Non-Voting Convertible Preferred Stock – $0.0001 par value; 223.7337 and -0- shares authorized at December 31, 2025 and 2024, respectively; 223.7337 and -0- shares issued and outstanding at December 31, 2025 and 2024, respectively	—	—
Common stock – $0.0001 par value, 290,000,000 shares authorized at December 31, 2025 and 2024; 916,968 and 36,753 shares issued and outstanding at December 31, 2025 and 2024, respectively	92	4
Additional paid-in capital	108,198,366	61,183,178
Accumulated deficit	(97,862,992)	(63,201,916)
Total stockholders' equity (deficit)	10,335,466	(2,018,734)
Total liabilities, Series A Non-Voting Convertible Preferred Stock and stockholders' equity (deficit)	$ 162,398,689	$ 7,294,499

See accompanying notes to the consolidated financial statements.

TRANSCODE THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2025	2024
Operating expenses		
Research and development	$ 13,421,848	$ 9,706,358
General and administrative		
General and administrative expenses	5,771,063	5,954,339
Acquisition-related transaction costs	8,787,160	—
Total general and administrative	14,558,223	5,954,339
Total operating expenses	27,980,071	15,660,697
Operating loss	(27,980,071)	(15,660,697)
Other income (expense)		
Change in fair value of warrant liabilities	(9,277,321)	(938,690)
Change in fair value of contingent consideration	1,584,000	—
PIPE warrant issuance costs	—	(596,957)
Grant income	1,277,867	524,064
Gain on sale of equipment	—	500
Currency exchange gain (loss)	(112,065)	(57,062)
Interest income	79,198	684
Interest expense	(6,616)	(26,813)
Total other income (expense)	(6,454,937)	(1,094,274)
Loss before income taxes	(34,435,008)	(16,754,971)
Deferred income tax provision	(226,068)	—
Net Loss	(34,661,076)	(16,754,971)
Deemed dividend arising from warrant modification	—	(30,601)
Accrual of paid-in-kind dividends on Series A Non-Voting Convertible Preferred Stock	(1,610,211)	—
Net loss attributable to common stockholders	$ (36,271,287)	$ (16,785,572)
Basic and diluted net loss per share		
Net loss attributable to common stockholders	$ (36,271,287)	$ (16,785,572)
Weighted-average common shares outstanding	689,713	12,558
Net loss per share	$ (52.59)	$ (1,336.63)

See accompanying notes to the consolidated financial statements.

TRANSCODE THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN SERIES A NON-VOTING CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
Years Ended December 31, 2025 and 2024

	Series A Non-Voting Convertible Preferred Stock		Series B Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2023	—	$ —	—	$ —	679	$ —	$ 48,057,158	$ (46,416,344)	$ 1,640,814
Issuance of common stock, net of offering costs	—	—	—	—	36,074	4	11,395,420	—	11,395,424
Deemed dividend arising from warrant modification	—	—	—	—	—	—	30,601	(30,601)	—
Share based compensation	—	—	—	—	—	—	1,699,999	—	1,699,999
Net loss	—	—	—	—	—	—	—	(16,754,971)	(16,754,971)
Balance, December 31, 2024	—	—	—	—	36,753	4	61,183,178	(63,201,916)	(2,018,734)
Issuance of Series A Preferred Stock in connection with the acquisition of Polynoma, net of issuance costs	1,152.9568	133,097,333	—	—	—	—	—	—	—
Proceeds from issuance of Series B preferred stock, net of issuance costs	—	—	223.7337	—	—	—	22,668,324	—	22,668,324
Transaction costs paid through the issuance of Series A Preferred Stock	59.2254	6,836,992	—	—	—	—	—	—	—
Issuance of common stock, net of offering costs	—	—	—	—	880,215	88	10,087,326	—	10,087,414
Exercise of Series D warrants	—	—	—	—	—	—	15,384,321	—	15,384,321
Accrual of paid-in-kind dividends on Series A Non-Voting Convertible Preferred Stock	—	1,610,211	—	—	—	—	(1,610,211)	—	(1,610,211)
Share based compensation	—	—	—	—	—	—	485,428	—	485,428
Net loss	—	—	—	—	—	—	—	(34,661,076)	(34,661,076)
Balance, December 31, 2025	1,212.1822	$ 141,544,536	223.7337	$ —	916,968	$ 92	$ 108,198,366	$ (97,862,992)	$ 10,335,466

See accompanying notes to the consolidated financial statements.

TRANSCODE THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (34,661,076)	$ (16,754,971)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	76,446	90,894
Amortization of right-of-use asset	37,731	443,963
Non-cash transaction costs	6,836,992	—
Share-based compensation expense	485,428	1,699,999
Change in fair value of contingent consideration	(1,584,000)	—
Change in fair value of warrant liabilities	9,277,321	938,690
PIPE warrant issuance cost	—	596,957
Due from related parties	(638)	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	477,261	405,573
Accounts payable and accrued expenses	216,541	(343,123)
Deferred grant income	(25,408)	(1,649)
Grants receivable	(952,460)	—
Security deposit	111,856	—
Operating lease liability	(38,291)	(412,280)
Deferred Tax Liability	226,068	—
Net cash used in operating activities	(19,516,229)	(13,335,947)
Cash flows from investing activities:		
Cash acquired through the acquisition of Polynoma	2,224	—
Purchase of equipment	(6,660)	(21,761)
Net cash used in investing activities	(4,436)	(21,761)
Cash flows from financing activities:		
Proceeds from offering of preferred stock (Series B), net of offering costs	22,668,324	—
Net proceeds from sales of common stock	8,854,798	16,401,174
Net cash provided by financing activities	31,523,122	16,401,174
Net change in cash	12,002,457	3,043,466
Cash, beginning of year	5,811,064	2,767,598
Cash, end of year	$ 17,813,521	$ 5,811,064
Supplemental disclosure of cash flow		
Cash paid during the period for:		
Interest related to insurance premium payment plan	$ 6,501	$ 16,629
Supplemental disclosure of non-cash investing and financing activities:		
Deemed dividend arising from warrant modification	$ —	$ 30,601
Recognition of liability classified Series C warrants	$ —	$ 448,478
Recognition of liability classified Series D warrants	$ —	$ 4,557,272
Exercise of Series D warrants	$ 15,384,319	$ —
Accrual of paid-in-kind dividends on Series A Non-Voting Convertible Preferred Stock	$ 1,610,211	$ —
Preferred stock issued in connection with acquisition of Polynoma	$ 133,097,333	$ —
Common stock issued in connection with acquisition of Polynoma	$ 1,232,618	$ —

See accompanying notes to the consolidated financial statements.

(1) Nature of Business and Liquidity

TransCode Therapeutics, Inc. (the "Company" or "TransCode") was incorporated on January 11, 2016, under the laws of the State of Delaware. TransCode is a clinical-stage biopharmaceutical company focused primarily on the research and development ("R&D") of innovative drugs for treating cancer. The Company operates in one segment. Its lead therapeutic candidate, TTX-MC138, comprises an oligonucleotide conjugated to an iron oxide nanoparticle designed to be administered by infusion to inhibit the ability of metastatic tumor cells to survive. The goal of the therapy, if approved, is to achieve durable disease regression, progression-free survival and long-term patient survival. The Company has other cancer therapy candidates in its pipeline. The Company completed its initial public offering ("IPO") on July 13, 2021.

On October 8, 2025, the Company entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") with DEFJ, LLC, a Delaware limited liability company, ("DEFJ") pursuant to which the Company acquired 100% of the issued and outstanding membership interests of ABCJ, LLC, a Delaware limited liability company, ("ABCJ") (such transaction, the "Acquisition"). Prior to the Acquisition, ABCJ was a wholly owned subsidiary of DEFJ and an indirect wholly owned subsidiary of CK Life Sciences Int'l., (Holdings) Inc. ("CKLS"), a listed entity on the Main Board of the Hong Kong Stock Exchange. In the Acquisition, the Company issued approximately 1,153 shares of its Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share, (the "Series A Preferred Stock").

ABCJ owns 100% of the issued and outstanding membership interests of Polynoma, LLC, a Delaware limited liability company, ("Polynoma") previously headquartered in San Diego, California. Polynoma is an immuno-oncology focused biopharmaceutical company developing Seviprotimut-L, an investigational polyvalent antigen vaccine intended to reduce the risk of recurrence of melanoma in patients in stage IIB and IIC who have limited options. Seviprotimut-L has been safely administered to more than 1,000 patients in clinical trials.

Concurrent with the Acquisition, the Company entered into an Investment Agreement (the "Investment Agreement") with DEFJ. Pursuant to the Investment Agreement, DEFJ purchased in a private placement an aggregate of approximately 224 shares of the Company's Series B Non-Voting Convertible Preferred Stock, par value $0.0001 per share, (the "Series B Preferred Stock" and, together with the Series A Preferred Stock, the "Preferred Stock") for a price per share of $111,740, or an aggregate purchase price of approximately $25 million. The aggregate purchase price consisted of a $20 million cash subscription paid on October 8, 2025, and a promissory note (the "Promissory Note") in the aggregate principal amount of approximately $5 million (together, the "October 2025 Investment"). The Promissory Note had a principal amount of approximately $5 million and accrued interest at a rate of 4% per annum, calculated as simple interest on a 365-day year. The principal and accrued interest were paid on December 30, 2025.

The Company intends to work on developing both TTX-MC138 and Seviprotimut-L, with its primary initial focus on advancing TTX-MC138 in a planned Phase 2a clinical trial. The Company believes there is potential to augment Seviprotimut-L's focus with TTX-MC138 by addressing micrometastases in stage IIB and IIC melanoma patients.

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

The Company plans to expand development of its lead therapeutic candidate and other candidates, and to explore strategic partnerships.

To further support its planned operations, the Company will require additional capital; however, the Company cannot be certain that additional funding will be available on acceptable terms, or at all. Through the date of these consolidated financial statements, the Company's primary source of capital was from the sale of equity securities in its IPO and subsequent financings, sales of convertible promissory notes prior to the IPO, and funds received under SBIR Awards. For the foreseeable future, the Company plans to fund its operations by continuing to raise additional capital, primarily through sales of equity or debt, and from funds that may be awarded under government and other grants.

(1) Nature of Business and Liquidity (continued)

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

Going Concern

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

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

For the year ended December 31, 2025, consolidated net cash used in operating activities was approximately $19.5 million and the Company's consolidated net loss was approximately $34.7 million. As of December 31, 2025, the Company had a consolidated accumulated deficit of approximately $97.9 million and approximately $17.8 million in cash.

Management believes that its cash at December 31, 2025, along with receipt of an obligation of DEFJ to reimburse approximately $2.3 million of certain expenses that the Company expects to receive in the first half of 2026 are sufficient to fund operations and capital requirements to approximately year end 2026.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation

These consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, ABCJ, LLC, including ABCJ's wholly owned subsidiaries, Polynoma, LLC and Polynoma, Inc. All intercompany accounts and transactions have been eliminated in consolidation.

(b) Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and liabilities, at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and

(2) Summary of Significant Accounting Policies (continued)

timing of future cash inflows and outflows. Significant items subject to such estimates and assumptions include but are not limited to estimated work performed but not yet billed by contract manufacturers and clinical research organizations, the valuation of equity and stock-based instruments, the valuation allowance related to deferred taxes, the estimated fair value of the net assets acquired in connection with the Acquisition, contingent value rights ("CVRs") issued to common stockholders at October 20, 2025, in connection with the Acquisition, the estimated fair value of the contingent consideration agreed to in connection with the Acquisition, share-based compensation, valuation of warrant liability, income from grants, and accrued research and development costs. Future events and their effects cannot be predicted with certainty; accordingly, accounting estimates require the exercise of judgment. These judgments can be subjective and complex. Accounting estimates used in the preparation of these financial statements change as new events occur, as more experience is acquired, as additional information is obtained and as the operating environment changes. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may materially vary from these estimates.

(c) Basic and Diluted Loss per Share

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

(d) Cash

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

(e) Fair Value Measurements

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

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

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

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

The Company's consolidated financial instruments as of the balance sheet dates included cash, grant receivable, due from related party, prepaid expenses and other current assets, goodwill, intangible assets, right-of-use asset, accounts payable and accrued expenses, deferred grant income, current and long-term portion of lease liability, warrant liability, and contingent consideration. Cash is reported at fair value. The recorded carrying amounts of grant receivable, due from related party, prepaid expenses and other current assets, goodwill, intangible assets, right-of-use asset, accounts payable and accrued expenses, deferred grant income, current and long-

(2) Summary of Significant Accounting Policies (continued)

term portion of lease liability, warrant liability, and contingent consideration approximate their fair value due to their short-term or fixed arrangements nature.

(f) Research and Development

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

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

Patent Costs

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

(g) Grant Income

Funds from grants are recognized as grant income in the statements of operations as and when earned for the specific research and development projects for which the grants are designated. In April 2021 and September 2024, the Company received awards (the "Awards") from the National Cancer Institute in support of the Company's lead therapeutic candidate. Since there is no transfer of ownership of the work performed under the Awards, and the Company does not lose control over the work performed under the Awards, the Company deems the Awards funds as contributions. Grant payments received in excess of grant income earned are recorded as deferred grant income on the Company's balance sheets until the related income has been earned. Grant income earned in excess of grant payments received is recorded as grant receivable on the Company's balance sheets.

(h) Share-Based Compensation

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

The estimated fair value of the common stock used by the Company to determine the expense of option awards is the closing Nasdaq price of the Company's common shares on the date of each award. Other factors used in calculating the fair value of share-based awards represented management's best estimates, some of which involve inherent uncertainties and the application of management's judgment. As a result, if factors were to change and management were to use different assumptions, share-based compensation expense could be materially different.

(2) Summary of Significant Accounting Policies (continued)

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

(i) Property and Equipment

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

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

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

(j) Income Taxes

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

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

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

(k) Emerging Growth Company Status

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

(2) Summary of Significant Accounting Policies (continued)

(l) Reverse Stock Splits

On May 23, 2023, the Company effected a reverse split of the Company's common stock, either issued and outstanding or held by the Company as treasury stock, (the "2023 Reverse Split") previously approved by the Company's Board of Directors ("Board") and stockholders of the Company. The 2023 Reverse Split was at a ratio of one share for every 20 shares previously held with no change in the par value per share. The 2023 Reverse Split did not change the number of authorized shares of common stock.

On January 16, 2024, the Company effected a reverse split of the Company's common stock, either issued and outstanding or held by the Company as treasury stock, (the "January 2024 Reverse Split") previously approved by the Board and stockholders of the Company. The January 2024 Reverse Split was at a ratio of one share for every 40 shares previously held with no change in the par value per share. The January 2024 Reverse Split did not change the number of authorized shares of common stock.

On December 4, 2024, the Company effected a reverse split of the Company's common stock, either issued and outstanding or held by the Company as treasury stock, (the "December 2024 Reverse Split") previously approved by the Board and stockholders of the Company. The December 2024 Reverse Split was at a ratio of one share for every 33 shares previously held with no change in the par value per share. The December 2024 Reverse Split did not change the number of authorized shares of common stock.

On May 15, 2025, the Company effected a reverse split of the Company's common stock, either issued and outstanding or held by the Company as treasury stock, (the "May 2025 Reverse Split") previously approved by the Board and stockholders of the Company. The May 2025 Reverse Split was at a ratio of one share for every 28 shares previously held with no change in the par value per share. The May 2025 Reverse Split did not change the number of authorized shares of common stock.

All common stock share and per share data, and exercise price data for applicable common stock equivalents, included in these consolidated financial statements have been retroactively adjusted to reflect the foregoing reverse stock splits.

(m) Collaboration Agreements

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

(2) Summary of Significant Accounting Policies (continued)

(n) Leases

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

(o) Warrant Accounting

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, "Distinguishing Liabilities from Equity" ("ASC 480"), and ASC 815, "Derivatives and Hedging" ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own ordinary shares and whether warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end-date while the warrants are outstanding.

(2) Summary of Significant Accounting Policies (continued)

For issued or modified warrants that meet all the criteria for equity classification, the warrants are required to be recorded as a component of equity at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as liabilities at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of warrants classified as liabilities are recognized as a non-cash gain or loss on the statements of operations.

Warrants issued upon financings in January and July 2024 and in March 2025 met the criteria for equity classification under ASC 815 and were classified as equity. Warrants issued upon a financing that closed December 2, 2024, did not meet the criteria for equity classification under ASC 815 and were classified as liabilities.

(p) Business Combinations

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, meeting the requirements of a business. If determined to be a business combination, the Company accounts for the transaction under the acquisition method of accounting as indicated in ASU 2017-01, "Business Combinations" ("ASC 805"), which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquiree, and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations based on fair value estimates as of their acquisition date. In accordance with ASC 805, the Company recognizes and measures goodwill as of the acquisition date, determined as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

(q) Indefinite-Lived Intangible Assets

Indefinite-lived intangible assets consist of In-Process Research and Development ("IPR&D"). The fair values of IPR&D project assets acquired in business combinations are capitalized. The Company generally utilizes the Multi-Period Excess Earning Method to determine the estimated fair value of the IPR&D assets acquired in a business combination. The projections used in this valuation approach are based on many factors, such as relevant market size, the estimated probability of regulatory success rates, anticipated patent protection, expected pricing, the population expected to be treated, and estimated payment obligations due from the Company (e.g., royalties). The estimated future net cash flows are then discounted to their present value using an appropriate discount rate. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate.

Intangible assets with indefinite lives, including IPR&D, are tested for impairment at least annually on October 1 and whenever facts and circumstances indicate that their carrying amounts may not be recoverable. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset's fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. The Company considers many factors in evaluating whether the value of its intangible assets with indefinite lives may not be recoverable, including, but not limited to, expected growth rates, the cost of equity and debt capital, general economic conditions, outlook and market performance of the Company's industry and recent and forecasted financial performance.

For the year ended December 31, 2025, the Company determined that there was no impairment to IPR&D.

(2) Summary of Significant Accounting Policies (continued)

(r) Goodwill

Goodwill represents the amount of consideration paid in excess of the fair value of net assets acquired as a result of the Company's business acquisitions accounted for using the acquisition method of accounting. The intangible assets acquired represented the fair value of IPR&D which has been recorded on the Company's consolidated balance sheet as indefinite-lived intangible assets. A deferred tax liability was recorded for the difference between the fair value of the acquired IPR&D and its tax basis which was recognized as goodwill in applying the purchase method of accounting. Goodwill is not amortized and is subject to impairment testing at least annually on October 1 and whenever facts and circumstances indicate that its carrying amount may not be recoverable. An entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that the fair value of the goodwill is less than its carrying amount.

For the year ended December 31, 2025, the Company determined that there was no impairment to goodwill.

(s) Impairment of Long-Lived Assets

In accordance with ASC 360-10-35, "Impairment or Disposal of Long-Lived Assets," the Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable (i.e., its carrying amount has been impaired). Once an impairment is determined, the actual impairment recognized is the difference between the carrying amount and the fair value (less costs to sell for assets to be disposed of) as estimated using one of the following approaches: income, cost, and/or market. Fair value using the income approach is determined primarily using a discounted cash flow model that uses the estimated cash flows associated with the asset or asset group under review, discounted at a rate commensurate with the risk involved. Fair value utilizing the cost approach is determined based on the replacement cost of the asset reduced for, among other things, depreciation and obsolescence. Fair value utilizing the market approach benchmarks the fair value of the asset against its carrying amount.

(t) Redeemable and Convertible Preferred Stock

The Company applies ASC 480 when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' equity (deficit). See Note 12 to these consolidated financial statements.

(u) Contingent Consideration

The Company applies ASC 805, "Business Combinations." ASC 805 requires recognition of assets acquired, liabilities assumed, and non-controlling interest in the acquired entity at the acquisition date, measured at their fair values as of that date. This ASC also requires that the fair value of contingent consideration be recorded on the acquisition date with subsequent changes in fair value charged in the statement of operations. In connection with the Acquisition, the Company agreed to make milestone payments contingent upon the achievement of certain events within ten (10) years of the date of the Acquisition. The Company estimated the fair value of contingent consideration incurred on the date of the Acquisition using the following inputs: the amount of each of the potential contingent payments, the estimated probability of success of achieving each milestone, and selection of the discount rate applied to the contingent payments.

(2) Summary of Significant Accounting Policies (continued)

(v) Recently Adopted Accounting Standards

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") and are adopted by the Company as of the specified effective date.

In December 2023, the FASB issued ASU No. 2023-09, "Improvements to Income Tax Disclosures," ("ASU 2023-09") which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. The Company adopted ASU 2023-09 for the year ended December 31, 2025.

(w) Recent Accounting Pronouncements

Unless otherwise discussed, the Company believes that the impact of recently issued accounting pronouncements will not have a material impact on the Company's consolidated financial position, consolidated results of operations, and consolidated cash flows, or do not apply to its operations.

In November 2024, the FASB issued ASU No. 2024-03, "Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures: Disaggregation of Income Statement Expenses" ("ASU 2024-03"). ASU 2024-03 will require more detailed information about the types of expenses in commonly presented income statement captions such as "Cost of sales" and "Selling, general and administrative expenses". The new guidance is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact that this change will have on the Company's disclosures.

In May 2025, the FASB issued ASU 2025-03, "Business Combinations (Topic 805)" and "Consolidation (Topic 810): Determining the Accounting Acquirer in the Acquisition of a Variable Interest Entity," to improve the requirements for identifying the accounting acquirer in Topic 805, "Business Combinations." The amendments in ASU 2025-03 revise current guidance for determining the accounting acquirer for a transaction effected primarily by exchanging equity interests in which the legal acquiree is a variable interest entity ("VIE") that meets the definition of a business. The amendments require that an entity consider the same factors that are currently required for determining which entity is the accounting acquirer in other acquisition transactions. Entities will be required to apply the new guidance prospectively to any acquisition transaction that occurs after the initial application date. Adoption of this guidance is effective for all entities for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods; early adoption is permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the impact of this ASU on its consolidated financial statements.

(3) Business Combination

On October 8, 2025, the Company entered into the Purchase Agreement with DEFJ pursuant to which the Company acquired 100% of the issued and outstanding membership interests of ABCJ (such transaction, the "Acquisition"). Prior to the Acquisition, ABCJ was a wholly-owned subsidiary of DEFJ and an indirect wholly-owned subsidiary of CKLS. The Company determined that ABCJ was a Variable Interest Entity ("VIE") and the Company is the primary beneficiary and the accounting acquirer.

Under the terms of the Purchase Agreement, on October 8, 2025, (the "Closing") in exchange for all of the the issued and outstanding membership interests of ABCJ immediately prior to the effective time of the Closing (the "Effective Time"), the Company issued to DEFJ, as sole member of ABCJ, an aggregate of (A) 83,285 shares of the Company's unregistered Common Stock, which shares represented no more than 9.99% of the outstanding shares of the Company's Common Stock immediately before the Effective Time and (B) 1,152.9568 shares of the Company's unregistered Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share, ("Series A Preferred Stock") (as described below). Each share of Series A Preferred Stock is convertible into 10,000 shares of Common Stock, subject to certain conditions described in the Purchase Agreement.

(3) Business Combination (continued)

The Board approved the Purchase Agreement and the related transactions, and the consummation of the Acquisition was not subject to approval of Company stockholders. Pursuant to the Purchase Agreement, the Company agreed to hold a stockholders' meeting to submit to its stockholders certain matters for their consideration, including: (i) approval of the conversion of shares of Series A Preferred Stock into shares of Common Stock in accordance with the rules of the Nasdaq Stock Market LLC ("Nasdaq") (the "Conversion Proposal"); (ii) approval of the conversion of shares of Series B Preferred Stock into shares of Common Stock in accordance with Nasdaq rules (the "Investment Proposal") and (iii) approval of a "change of control" under Nasdaq Listing Rules 5110 and 5635(b) (the "Change of Control Proposal"); and together with the Conversion Proposal and the Investment Proposal, the "Meeting Proposals"). In connection with these matters, the Company agreed to file a proxy statement on Schedule 14A with the SEC.

The fair value of the consideration totaled approximately $140.0 million, summarized as follows:

Fair value of contingent consideration	$	7,948,000
Reimbursement right asset		(2,297,806)
Fair value of common stock issued		1,232,618
Fair value of preferred stock issued		133,097,333
Total Consideration Paid	$	139,980,145

The transaction was accounted for as a Business Combination. Under this method, the total purchase price of the Acquisition is allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on fair values as of the date of the Acquisition. Consideration paid comprises the estimated fair value of various securities issued including the Series A Preferred Stock and the Common Stock issued to DEFJ. In the fourth quarter of 2025, the preliminary purchase price allocation was updated, including the related determination of fair value of the securities issued as consideration, the allocation of consideration to the specific in-process research and development programs acquired and the tax implications related to the updates to the purchase price allocation.

The Company recorded the assets acquired and liabilities assumed as of the date of the Acquisition based on the information available at that date. The following table presents the allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed as of the Acquisition date:

Assets acquired:		
Cash	$	2,224
Prepaid expenses and other current assets		114,427
Property and equipment, net of depreciation		388,894
In-process research and development assets: Seviprotimut-L		114,300,000
Goodwill		25,744,143
Total assets acquired	$	140,549,688
Liabilities Assumed:		
Accounts payable and accrued expenses	$	569,543
Deferred tax liability		—
Total liabilities assumed		569,543
Net assets acquired	$	139,980,145

The fair value of in-process research and development assets ("IPR&D") was capitalized as of the Acquisition date and accounted for as indefinite-lived intangible assets until completion or disposition of the assets or abandonment of the associated research and development efforts. Upon successful completion of the development efforts, the useful lives of the IPR&D assets will be determined based on the anticipated period of regulatory exclusivity and will be amortized within operating expenses. Until that time, the IPR&D assets will be subject to impairment testing and will not be amortized. The goodwill recorded related to the acquisition is the excess of

(3) Business Combination (continued)

the fair value of the consideration transferred by the acquirer over the fair value of the net identifiable assets acquired and liabilities assumed at the date of the Acquisition. The goodwill recorded is not deductible for tax purposes.

The following table summarizes the Company's intangible assets and goodwill acquired in connection with the Acquisition and their carrying value as of December 31, 2025.

	Acquisition Date Level 3 Fair Value	Impairment	Carrying Value as of December 31, 2025
Seviprotimut-L	$ 114,300,000	$ —	$ 114,300,000
Total in-process research and development (IPR&D)	$ 114,300,000	$ —	$ 114,300,000
Goodwill	$ 25,744,143	$ —	$ 25,744,143

Intangible asset fair values for the IPR&D program were determined using the Multi-Period Excess Earnings Method ("MPEEM") which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset's incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life. To calculate fair value of acquired IPR&D programs under the MPEEM, the Company uses probability-weighted cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by development-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to each program and then reduced by a contributory charge on requisite assets employed. Contributory assets included debt-free working capital, net fixed assets and assembled workforce. Rates of return on the contributory assets were based on rates used for comparable market participants. Cash flows were assumed to extend through the market exclusivity period expected to be provided by trade-secrets and patents or for products related to the indication to be treated. The resultant cash flows were then discounted to present value using a weighted-average cost of equity capital for companies with profiles substantially similar to that of the acquired IPR&D program, which the Company believes represents the rate that market participants would use to value the assets. The Company compensated for the phase of development of the program by probability-adjusting its estimation of the expected future cash flows. The projected cash flows were based on significant assumptions, such as the time and resources needed to complete development and approval of the IPR&D program, estimates of revenues and operating profits related to the program considering its stage of development, the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in drug development, such as obtaining marketing approval from the FDA and other regulatory agencies, and risks related to the viability of and potential alternative treatments in any future target markets.

The Company's transaction costs of approximately $8.8 million include direct expenses incurred in connection with the Acquisition, as well as integration-related professional fees and other incremental costs directly associated with the Acquisition. Transaction costs were expensed as incurred and are included in General and Administration expenses in the Company's consolidated statement of operations.

(4) Fair Value Measurements

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

The Company records its warrant liability at fair value which is considered a Level 3 measurement on the fair value hierarchy due to the significant unobservable inputs used in valuation of the warrant liability such as the probability weighted outcomes regarding the shareholder approval date and the potential de-listing date. The fair value of the warrant liability at issuance and at December 31, 2024, was determined using a Monte Carlo simulation model within a risk-neutral framework. This widely accepted financial modeling approach is employed to value complex instruments, including warrants with strike price reset and anti-dilution provisions. The model simulates multiple potential future paths for the Company's stock price, accounting for the reset provision by adjusting the strike price if the stock price falls below a specified level, but not lower than the specified Floor Price. Upon each reset of the strike price, the warrants are also adjusted for quantity, based on the anti-dilution provisions. For each simulated path, the warrants' payoff is calculated using the final stock price and the potentially adjusted strike price and quantity, then discounted to present value. The fair value is estimated as the average of these discounted payoffs across all simulated paths. This method ensures the valuation reflects the impact of the strike price reset provision and anti-dilution provision on the warrants' potential values. Fair value of the warrant liability as of December 31, 2025, was determined using the Black-Scholes valuation model which the Company deemed appropriate as both the exercise price of the warrants and the number of shares issuable were known, no longer requiring use of a simulation model.

The table below lists key assumptions used in the valuations of the warrant liability as of December 31, 2025 and 2024. The $434,399 fair value of the Series C Warrants as of December 31, 2025, was a decrease of $83,472 from December 31, 2024, which decrease was recorded as change in fair value of warrant liability.

Assumptions	December 31, 2025	December 31, 2024
Risk-free rate	3.64%	4.33%
Volatility	115.00%	150.00%
Expiration date of Series C	February 24, 2030	November 29, 2029
Expiration date of Series D	N/A	May 29, 2027
Shareholder approval date	N/A	February 25, 2025
Potential de-listing date	N/A	N/A

The following tables present the Company's assets and liabilities that are measured at fair value on a recurring basis.

The fair value of the specified liabilities at December 31, 2025, is as follows:

	Level 1	Level 2	Level 3	Total
Liabilities				
PIPE warrants - Series C	$ —	—	$ 434,399	$ 434,399
Contingent consideration	—	—	6,364,000	6,364,000
Total liabilities, at fair value	$ —	$ —	$ 6,798,399	$ 6,798,399

The fair value of the specified liabilities at December 31, 2024, is as follows:

	Level 1	Level 2	Level 3	Total
Warrant liabilities				
PIPE warrants - Series C	$ —	$ —	$ 517,871	$ 517,871
PIPE warrants - Series D	—	—	6,023,526	6,023,526
Total liabilities, at fair value	$ —	$ —	$ 6,541,397	$ 6,541,397

(4) Fair Value Measurements (continued)

Level 3 Rollforward:	Warrants Series C	Warrants Series D	Contingent Consideration	Total Liabilities
Balance, December 31, 2023	$ —	$ —	$ —	$ —
Additions	501,961	5,100,746	—	5,602,707
Change in fair value	15,910	922,780	—	938,690
Balance, December 31, 2024	517,871	6,023,526	—	6,541,397
Additions	—	—	7,948,000	7,948,000
Change in fair value	(83,472)	9,360,793	(1,584,000)	7,693,321
Exercise of Series D warrants	—	(15,384,319)	—	(15,384,319)
Balance, December 31, 2025	$ 434,399	$ —	$ 6,364,000	$ 6,798,399

The Company incurred contingent consideration in connection with the Acquisition. It records its contingent consideration liability at fair value which is considered a Level 3 measurement on the fair value hierarchy due to the significant unobservable inputs used in valuation of the contingent consideration liability such as the probability of milestone events being achieved and the time to payment of potential milestone events. The fair value of the contingent consideration liability at issuance and at December 31, 2025, was determined using a discounted cash flow analysis. The table below lists key assumptions used in the valuations as of December 31, 2025, and October 8, 2025 (the date of the Acquisition). The $6,364 thousand fair value of the contingent consideration at December 31, 2025, was a decrease of $1,584 thousand from October 8, 2025, which decrease was recorded as change in fair value of contingent consideration.

Assumptions	December 31, 2025	October 8, 2025
Expected achievement date of milestone event #1	June 30, 2029	June 30, 2029
Probability of achieving milestone event #1	90.00%	90.00%
Discount rate applied to milestone event #1	15.60%	11.30%
Expected achievement date of milestone event #2	June 30, 2036	June 30, 2036
Probability of achieving milestone event #2	42.90%	42.90%
Discount rate applied to milestone event #2	15.40%	12.50%
Expected achievement date of milestone event #3	June 30, 2042	June 30, 2042
Probability of achieving milestone event #3	42.90%	42.90%
Discount rate applied to milestone event #3	15.40%	13.10%
Expected achievement date of milestone event #4	June 30, 2043	June 30, 2043
Probability of achieving milestone event #4	39.50%	39.50%
Discount rate applied to milestone event #4	15.40%	13.20%

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31, 2025	December 31, 2024
Prepaid operating expenses	$ 31,901	$ 31,563
Contract manufacturers and research organizations	242,976	517,484
Insurance premiums	286,064	310,735
Prepaid FICA	358,499	422,492
	$ 919,440	$ 1,282,274

(6) Property and Equipment

Property and equipment, net consisted of the following:

	December 31, 2025	December 31, 2024
Laboratory and computer equipment	$ 757,941	$ 362,387
Less accumulated depreciation	(387,260)	(310,813)
Total property and equipment, net	$ 370,681	$ 51,574

Depreciation expense for the years ended December 31, 2025 and 2024 was $76,446 and $90,894, respectively.

(7) Receivable from Related Party

On October 8, 2025, under the Purchase Agreement, DEFJ agreed to reimburse the Company for up to $3 million of specified Polynoma-related expenses incurred in the fourth quarter of 2025 expenses. The Company has invoiced DEFJ for approximately $2.3 million of such expenses incurred through or related to activities initially arising prior to December 31, 2025.

There was no comparable reimbursement arrangement at or for the year ended December 31, 2024.

(8) Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	December 31, 2025	December 31, 2024
Professional and general consulting fees	$ 1,086,260	$ 1,282,428
R&D-related – CMOs, CROs, supplies, equipment and consulting	1,958,208	1,148,917
General expenses	70,588	143,988
Insurance premiums	4,314	765
Payroll and benefits	374,850	131,342
Accrued license payments	—	697
	$ 3,494,220	$ 2,708,137

At December 31, 2025 and 2024, the Company's outstanding payables to CROs or CMOs included above were $1,443,486 and $997,074, respectively.

See Note 10 for further information regarding the accrued license payments.

(9) Grant Income

In September 2024, the Company received its second Award (the "2024 Award") from the National Cancer Institute of the National Institutes of Health (the "NIH"). The 2024 Award is a Direct to Phase II SBIR Award to support IND-enabling and clinical trial activities in the Company's clinical trial with its lead candidate, TTX-MC138, over two years. The total 2024 Award is for $1,999,972 of which $1,011,207 applies to the first year and $988,765 applies to the second year. Income under the grant is recognized as work under the grant is completed. The Company recognized grant income of $1,277,867 and $524,064 for the years ended December 31, 2025 and 2024, respectively. The Company recorded grant income receivable of $952,460 and $0 at December 31, 2025 and 2024, respectively. The Company had deferred grant income of $0 and $25,408 at December 31, 2025 and 2024, respectively.

(10) Commitments and Contingencies

(a) Leases

Operating Lease

In December 2022, the Company signed an agreement to sublease 4,837 square feet of laboratory and office space in Newton, Massachusetts, from another biopharmaceutical company. The Company considers this sublease an operating lease with estimated right-of-use assets and lease liabilities of $874,957 recorded upon lease commencement on February 1, 2023. The sublease had an initial term of 24 months, and the Company had the option to extend the sublease for an additional 12 months but did not elect to exercise the option. Because the Company did not believe that the exercise of this option was probable, it did not include it in determination of the lease amounts. The base monthly rent was $37,285 during the first 12 months of the lease and $38,403 in the second 12 months. In addition, the Company was responsible for its share of operating expenses, real estate taxes, and utilities based on the actual costs of these items. Upon termination of this lease on January 31, 2025, the Company relocated its business operations to another location under a six-month agreement for $3,520 per month with options to renew semi-annually.

Prior to February 1, 2023, and subsequent to January 31, 2025, the Company had no operating leases with maturities greater than one year. The Company does not recognize any variable lease costs or short-term lease costs in connection with the operating lease.

Rent expense for the years ended December 31, 2025 and 2024, was $107,344 and $411,662, respectively.

(b) License Agreements

License One

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

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

(10) Commitments and Contingencies (continued)

Milestone payments payable by the Company are summarized below.

Milestone Event		Amount
1. Enrollment of first patient in a phase II clinical trial of a therapeutic product or process	$	[**]
2. Enrollment of first patient in a phase III clinical trial of a therapeutic product or process	$	[**]
3. First commercial sale of a therapeutic product or process	$	[**]
4. Filing of an application for regulatory approval of a clinical diagnostic product or process	$	100,000
5. First regulatory approval of a clinical diagnostic product or process	$	150,000
6. Change of Control Liquidity Event:		
a. between $50 million and $100 million, or	$	[**]
b. greater than $100 million	$	[**]

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

In November 2020, the Company and Licensor amended the November 2018 license. Under the amendment, the intellectual property licensed in 2018 was categorized as “Patent Family 1” and a provisional patent filing related to the Company’s nanoparticle technology was added to Patent Family 1. A second patent family (“Patent Family 2”) was created which includes Licensor intellectual property targeting PD-L1. The minimum annual license fee prior to the first commercial sale of a product or process covered by the License was increased from $25,000 per year to $30,000 per year for Patent Family 1 and a minimum annual license fee of $10,000 per year was added related to Patent Family 2. All other terms of the License including milestone payments, royalties and payment terms related to sublicense income received by the Company remain the same as in the original License.

Effective August 15, 2025, the Company and Licensor further amended the License (the “Second Amendment”) to revise the diligence requirements and milestone payments. In connection with the Second Amendment, Company paid Licensor a license amendment fee of $75,000. The Second Amendment revised certain one-time milestone payments to be made by Company to Licensor for Products and Processes covered by the License as follows:

(i) a certain dollar amount within sixty (60) days following dosing of the first patient in the first phase II clinical trial for a Therapeutic Product or Therapeutic Process for each Patent Family;

(ii) a certain dollar amount within sixty (60) days following dosing of the first patient in the first phase III clinical trial for a Therapeutic Product or Therapeutic Process for each Patent Family; and

(iii) a certain dollar amount within sixty (60) days following the First Commercial Sale for a Therapeutic Product or Therapeutic Process for each Patent Family.

In addition, upon the occurrence of a Change of Control Liquidity Event (as defined in the Second Amendment), the Company shall pay Licensor up to a certain dollar amount.

The License One milestone payments the Company shall pay to Licensor shall not exceed $2,950,000 based upon and subject to the attainment of each milestone event. These payments are generally due within 60 days of achievement of the milestone.

As of December 31, 2025 and 2024, no License One milestone events had been achieved.

License Two

The Company’s second license is between Polynoma, LLC and Sloan Kettering Institute (“SKI”) For Cancer Research (the “SKI License”). The SKI License was entered into on April 12, 2006, by SKI and MAANEX LLC, a predecessor of Polynoma. Under the SKI License, there are the following Milestone Events (excluding milestones that occurred prior to the Company’s acquisition of Polynoma which prior milestones were previously paid):

(10) Commitments and Contingencies (continued)

Milestone Event		Amount
1. Upon filing of a New Drug Application (NDA) with the Food and Drug for a product(s) subject to the SKI License	$	50,000
2. Enrollment of first patient in a phase III clinical trial of a therapeutic product or process	$	125,000

As of December 31, 2025 and 2024, no License Two milestone events had been achieved.

Accrued License Obligations

At December 31, 2025 and 2024, the Company had accrued $0 and $697, respectively, in license payments under the foregoing arrangements included in accounts payable and accrued expenses.

(c) Collaboration Agreement

On July 29, 2022, the Company signed a five-year strategic collaboration agreement with The University of Texas M. D. Anderson Cancer Center ("MD Anderson"). Under the collaboration, the Company anticipated making certain expenditures with respect to Phase I and Phase II clinical trials which it expects will be conducted in part through MD Anderson as a primary investigator site. MD Anderson was also to provide preclinical work under the collaboration. The details of clinical and preclinical work were to be mutually agreed by the parties prior to commencing work. The Company committed to fund up to $10 million over the term of the collaboration. Of this amount, the initial payment schedule called for $500,000 to be paid within the first year. Subsequent payments were scheduled to be $2 million on the first anniversary of the effective date of the agreement and $2.5 million on each of the second, third and fourth anniversaries thereof. The $250,000 first payment made by the Company to MD Anderson in January 2023 was recorded as a Prepaid Expense pending such time as payments under the collaboration become due. In late 2024, the Company and MD Anderson agreed to amend the collaboration agreement in favor of MD Anderson focusing solely on participation in our Phase I/II clinical trial. This amendment relieved the Company from the obligation to make up to $10 million of collaboration payments. We are obligated to pay charges incurred by MD Anderson in connection with clinical trial services. Initial expenses of the clinical trial were charged against the initial payment made to MD Anderson. For the years ended December 31, 2025 and 2024, these charges were $154,306 and $279,768, respectively.

(d) Employment Agreements and Severance

Prior to the IPO, the Company entered into employment agreements with its executive officers which became effective on completion of the IPO. The employment agreements provide the employee with, among other things, severance payments upon termination of the agreement by the Company for any reason other than for cause, death or disability or by the employee for good reason. The maximum aggregate severance payments under the agreements, which arise in the event of termination involving a Change of Control (as defined in the agreements), are approximately $2,436,750.

In December 2023, the Board approved various actions designed to streamline the Company's operations and reduce expenses (the "Restructuring"). These included delaying or eliminating certain development activities and reducing headcount by laying off four employees. This lowered the Company's headcount to eight employees at December 31, 2024, compared to 11 at December 31, 2023. Severance in the aggregate of $424,576 was provided to the affected employees and charged to expense in 2024.

(e) Litigation

The Company may from time to time be subject to claims by others under various legal disputes. The defense of such claims, or any adverse outcome relating to any such claims, could have a material adverse effect on the Company's liquidity, consolidated financial condition, and consolidated cash flows. At the balance sheet dates herein, the Company did not know of any claims or actions pending against it or threatened, the ultimate disposition of which could have a material adverse effect on its consolidated results of operations or consolidated financial condition except claims by an investment bank that it is entitled to fees, claims which the Company rigorously disputes.

(10) Commitments and Contingencies (continued)

(f) Indemnification Agreements

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

(g) Risks and Uncertainties

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

(h) Contingent Value Rights Agreement

Concurrent with the Closing of the Acquisition, the Company entered into a contingent value rights agreement (the "CVR Agreement") with a rights agent (the "Rights Agent"), pursuant to which each holder of Common Stock as of October 20, 2025, including those holders receiving shares of Common Stock in connection with the Acquisition, was entitled to one contractual contingent value right (each, a "CVR") issued by the Company, subject to and in accordance with the terms and conditions of the CVR Agreement. The CVR Agreement has a term of seven years.

Each CVR entitles the holders thereof (each a "CVR Holder"), in the aggregate, to 50% of the Net Proceeds (as defined in the CVR Agreement) from any Upfront Payment (as defined in the CVR Agreement) or Milestone Payment (as defined in the CVR Agreement) received by the Company in a given calendar quarter. The distributions in respect of the CVRs that become payable will be made on a quarterly basis and will be subject to a number of deductions, subject to certain exceptions or limitations, including but not limited to for certain taxes and certain out-of-pocket expenses incurred by the Company.

Under the CVR Agreement, the Rights Agent has, and CVR Holders of at least 30% of the CVRs then-outstanding have, certain rights to audit and enforcement on behalf of all CVR Holders. The CVRs may not be sold, assigned, transferred, pledged, encumbered or in any other manner transferred or disposed of, in whole or in part, other than as permitted pursuant to the CVR Agreement. By virtue of holding CVRs, a CVR Holder does not have the rights of a stockholder and does not have the ability to vote, rights to dividends, or other interests. The CVRs also establish certain restrictions on mergers and change in control activities, as defined in the CVR Agreement.

As no transaction was deemed probable as of December 31, 2025, the Company has not recorded any potential liability related to the CVRs.

(11) Contingent Consideration

In connection with the Acquisition, the Company agreed to make up to $95,000,000 in contingent milestone payments (each, a "Milestone Payment" and collectively, the "Milestone Payments") (the "Acquisition Obligation") to DEFJ upon the achievement

(11) Contingent Consideration (continued)

within ten (10) years of the date of the Purchase Agreement of the following milestone events (each, a "Milestone Event") upon the first achievement by or on behalf of the Company (including any licensee or assignee of rights to commercialize the Seller Lead Candidate as defined in the Purchase Agreement) of the corresponding Milestone Event as follows: (i) a milestone payment of five million U.S. dollars ($5,000,000) upon the first dosing of the Seller Lead Candidate in a patient in a United States Phase 3 Clinical Study; (ii) a milestone payment of ten million U.S. dollars ($10,000,000) upon the achievement of the applicable primary endpoint in a United States Phase 3 Clinical Study of the Seller Lead Candidate; (iii) a milestone payment of twenty million U.S. dollars ($20,000,000) upon the first submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for the Seller Lead Candidate; and (iv) a milestone payment of sixty million U.S. dollars ($60,000,000) upon the first approval by the FDA of a BLA for the Seller Lead Candidate.

The estimated fair value of the Acquisition Obligation on the Effective Date and at December 31, 2025, was approximately $7.9 million and $6.4 million, respectively.

(12) Stockholders' Equity (Deficit)

(a) Overview

The Company's Certificate of Incorporation (the "Charter"), originally filed on January 11, 2016, was amended on April 15, 2020, to increase the number of shares of common stock authorized and to authorize the issuance of preferred stock. The Company's Certificate of Incorporation was further amended and restated on April 27, 2021, on May 22, 2023, to effect the May 2023 Reverse Split, on January 16, 2024, to effect the January 2024 Reverse Split, on December 4, 2024, to effect the December 2024 Reverse Split, and on May 5, 2025, to effect the May 2025 Reverse Split. The total number of shares which the Company is authorized to issue is 300,000,000, each with a par value of $0.0001 per share. Of these shares, 290,000,000 shall be common stock and 10,000,000 shall be preferred stock. The Company's restated Certificate of Incorporation, as amended, permits its Board to designate the number of shares constituting such series, and fix by resolution, the powers, privileges, preferences and relative, option or special rights thereof, including liquidation preferences and dividends, and conversion and redemption rights of each such series. A Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock and Series B Non-Voting Convertible Preferred Stock was filed on October 8, 2025, and amended on October 23, 2025, (as amended, the "Certificate of Designation") to give effect to the designation of the Series A Preferred Stock (as defined below) and Series B Preferred Stock (as defined below).

At December 31, 2025 and 2024, the Company had 916,968 and approximately 36,753 shares of common stock issued and outstanding, respectively. At December 31, 2025 and 2024, the Company had approximately 1,466 and zero shares of preferred stock issued and outstanding, respectively.

(b) Preferred Stock

In October 2025, the Board designated 1,242.0718 shares of preferred stock to be Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock"). As of December 31, 2025, the Company had authorized, issued and outstanding 1,212.1822 shares of Series A Preferred Stock. In October 2025, the Board designated 223.7337 of the 10,000,000 shares of preferred stock to be Series B Non-Voting Convertible Preferred Stock ("Series B Preferred Stock"). As of December 31, 2025, the Company had authorized, issued and outstanding 223.7337 shares of Series B Preferred Stock. As of December 31, 2025, the Company had authorized, issued and outstanding 1,435.9159 shares of preferred stock and 9,998,564.0841 authorized and unissued or outstanding shares of preferred stock.

As of April 6, 2026, Holders of Series A Preferred Stock were entitled to receive, and the Company paid, payment-in-kind dividends on each share of Series A Preferred Stock, at a rate equal to five percent (5.0%) per annum payable in shares of Series A Preferred Stock.

Except as otherwise required by law, the Series A Preferred Stock and Series B Preferred Stock do not have voting rights. However, as long as any shares of Series A Preferred Stock or Series B Preferred Stock are outstanding, the Company may not, without the

(12) Stockholders' Equity (Deficit) (continued)

affirmative vote of the holders of a majority of the then-outstanding shares of the Series A Preferred Stock and Series B Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or Series B Preferred Stock or alter or amend the Certificate of Designation, amend or repeal any provision of, or add any provision to, the Charter or Amended and Restated Bylaws of the Company, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of Preferred Stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series A Preferred Stock or Series B Preferred Stock, regardless of whether any of the foregoing actions shall be by means of amendment to the Charter or by merger, consolidation, recapitalization, reclassification, conversion or otherwise, (ii) issue further shares of Series A Preferred Stock or Series B Preferred Stock, or increase or decrease (other than by conversion) the number of authorized shares of Series A Preferred Stock or Series B Preferred Stock, (iii) prior to the Stockholder Approval (as defined in the Certificate of Designation) or at any time while at least 30% of the originally issued Series A Preferred Stock or Series B Preferred Stock, as applicable, remains issued and outstanding, consummate either: (A) any Fundamental Transaction (as defined in the Certificate of Designation) or (B) any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, or (iv) enter into any agreement with respect to any of the foregoing.

The Series A Preferred Stock and Series B Preferred Stock shall rank on parity with the Common Stock as to distributions of assets upon liquidation, dissolution or winding-up of the Company, whether voluntarily or involuntarily.

At any time following 5:00 p.m. Eastern Time on the third business day after the date the Company's stockholders approve the conversion of the Series A Preferred Stock and Series B Preferred Stock (the "Stockholder Approval"), each share of Series A Preferred Stock will be convertible at the option of the holder thereof into 10,000 shares of Common Stock, subject to certain limitations provided
in the Certificate of Designation, including that the Company shall not effect any conversion of Series A Preferred Stock into shares of Common Stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage of the total number of shares of Common Stock issued and outstanding immediately after giving effect to such conversion (the "Beneficial Ownership Limitation").

Upon the earliest to occur of (i) April 8, 2026, (ii) the effectiveness date of a registration statement covering the resale of the Common Stock issuable upon conversion of the Series B Preferred Stock, and (iii) 5:00 p.m. Eastern Time on the third business day after the date the Stockholder Approval is obtained, in each case at the option of the Holder thereof, each share of Series B Preferred Stock will be convertible, at any time and from time to time, into 10,000 shares of Common Stock, subject to certain limitations provided in the Certificate of Designation, including that the Company shall not effect any conversion of Series B Preferred Stock into shares of Common Stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own Common Stock in excess of the Beneficial Ownership Limitation.

At any time following the earlier to occur of (i) the receipt of the Stockholder Approval or (ii) the consummation of a Fundamental Transaction (as defined in the Certificate of Designation) the holders of Series A Preferred Stock and Series B Preferred Stock may waive or change the Beneficial Ownership Limitation effective upon written notice to the Company; provided, that to the extent such waiver or change is solely permitted pursuant to the Stockholder Approval or the consummation of a Fundamental Transaction, such notice must be delivered not less than 60 days prior to the effectiveness of such waiver or change.

Upon the occurrence of the conditions set forth in section 5.3 of the Repurchase Agreement dated as of October 8, 2025, by and between the Company and DEFJ (the "Repurchase Agreement"), or if the Company fails to deliver to the holder of Series A Preferred Stock a certificate or certificates representing shares of Common Stock, or electronically deliver such shares, (i) on or prior to the third trading day after the applicable Share Delivery Date (as defined in the Certificate of Designation), or (ii) April 8, 2027, then, unless the holder of Series A Preferred Stock has rescinded the applicable Notice of Conversion, the Company will, at the request of the holder of Series A Preferred Stock, pay an amount equal to the Fair Value (as defined in the Certificate of Designation) of such undelivered shares, with such payment to be made within two business days from the date of request by such holder, whereupon the Company's obligations to deliver such shares underlying the Notice of Conversion (as defined in the Certificate of Designation) shall

(12) Stockholders' Equity (Deficit) (continued)

be extinguished upon payment in full of the Fair Value of such undelivered shares; provided, however that such request shall be presumed to have been duly and properly made by such holder if Stockholder Approval with respect to the Series A Preferred Stock shall not have been obtained prior to the date on which the Notice of Conversion is delivered to the Company.

Upon the occurrence of the conditions set forth in section 5.3 of the Repurchase Agreement, or if the Company fails to deliver to the holder of Series B Preferred Stock a certificate or certificates representing shares of Common Stock, or electronically deliver such shares, on or prior to the third trading day after the applicable Share Delivery Date, then, unless the holder of Series B Preferred Stock has rescinded the applicable Notice of Conversion, the Company will, at the request of the holder of Series B Preferred Stock, pay an amount equal to the Fair Value of such undelivered shares, with such payment to be made within two business days from the date of request by such holder, whereupon the Company's obligations to deliver such shares underlying the Notice of Conversion shall be extinguished upon payment in full of the Fair Value of such undelivered shares; provided, however that such request shall be presumed to have been duly and properly made by such holder if Stockholder Approval with respect to the Series B Preferred Stock shall not have been obtained prior to the date on which the Notice of Conversion is delivered to the Company.

The cash settlement provisions set forth in the Certificate of Designation shall be available irrespective of the reason for the Company's failure to timely deliver the applicable shares of Common Stock including due to the lack of obtaining the Stockholder Approval with respect to the Preferred Stock.

(c) Repurchase Agreement

The terms of the Repurchase Agreement signed in connection with the Acquisition (the "Repurchase Agreement") provide that DEFJ has the right, but not an obligation, after the Closing and upon the occurrence of certain conditional events including continued listing requirements, to acquire all of the Company's and its subsidiaries' rights in and to the membership interests of ABCJ (the "Interests") from the Company in accordance with the terms and conditions of the Repurchase Agreement. The aggregate purchase price for the Interests (the "Repurchase Price") shall equal to one hundred percent (100%) of the Purchaser Preferred Stock Payment Shares (as defined in the Repurchase Agreement) (or the number of shares of Purchaser Common Stock shares issued upon conversion thereof) initially issued to DEFJ pursuant to the Purchase Agreement (the "Share Consideration").

(d) Redeemable Preferred Stock

The Company applies ASC 480 when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' equity.

(e) Series A Preferred Stock

In connection with the Acquisition, the Company initially issued 1,212.1822 shares of Series A Preferred Stock. The Series A Preferred Stock does not have voting rights except for voting on specific corporate matters including (i) changes to the rights and preferences of the Series A Preferred Stock, (ii) issuance of additional Series A Preferred Stock, and (iii) entry into a fundamental transaction such as a sale of the Company. Certain provisions of the Series A Preferred Stock are as follows:

(12) Stockholders' Equity (Deficit) (continued)

- Conversion: Upon obtaining stockholder approval at the Special Meeting, each share of Series A may convert into 10,000 shares of common stock, subject to Beneficial Ownership Limitations.

- Dividends: Series A Preferred Stock is eligible to participate in any dividends with common stockholders on an as-converted basis. On April 6, 2026, the Company issued to holders of Series A Preferred Stock a payment-in-kind dividend for each share of Series A Preferred Stock, which payment-in-kind dividend accrued at a rate equal to five percent (5.0%) per annum payable in shares of Series A Preferred Stock.

- Liquidation: In the event of the liquidation, dissolution, or winding up of the affairs of the Company (a "Liquidity Event"), prior to Stockholder Approval, holders of Series A Preferred Stock would be entitled to receive a liquidation preference prior to any payment to the holders of Common Stock.

- Redemption: In the event the Company is unable to obtain an affirmative stockholder vote at the Special Meeting to permit conversion, each holder of Series A Preferred Stock will be entitled to elect, at the holder's option, to have their shares of Series A Preferred Stock redeemed by the Company for an amount equal to the estimated fair value of the Series A Preferred Stock shares held by such holder at the time of redemption. Due to this redemption feature, as of December 31, 2025, the Series A Preferred Stock was classified within temporary equity on the consolidated balance sheet.

(f) Series B Preferred Stock

In connection with the Acquisition, the Company issued 223.7337 shares of Series B Preferred Stock. The Series B Preferred Stock does not have voting rights except for voting on specific corporate matters including (i) changes to the rights and preferences of the Series B Preferred Stock, (ii) issuance of additional Series B Preferred Stock, and (iii) entry into a fundamental transaction such as a sale of the Company. Certain provisions of the Series B Preferred Stock are as follows:

- Conversion: Each share of Series B Preferred Stock is convertible into 10,000 shares of Common Stock upon the earliest to occur of (i) April 8, 2026, (ii) the effectiveness date of a registration statement covering the resale of the Common Stock issuable upon conversion of the Series B Preferred Stock, and (iii) 5:00 p.m. Eastern time on the third business day after the date that the Stockholder Approval is obtained, at the option of the holder thereof, in each case subject to Beneficial Ownership Limitations.

- Dividends: Series B Preferred Stock is eligible to participate in any dividends with common stockholders on an as-converted basis

- Liquidation: In the event of a Liquidity Event prior to Stockholder Approval, holders of Series B Preferred Stock would be entitled to receive a liquidation preference prior to any payment to the holders of Common Stock.

(g) Common Stock

i. Dividends

Subject to the rights of holders of any preferred stock, holders of common stock are entitled to receive dividends as may be declared from time to time by the Board. The Company has never declared or paid cash dividends through the date of these consolidated financial statements.

ii. Liquidation

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

(12) Stockholders' Equity (Deficit) (continued)

iii. Voting

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

(h) Issuances of Common Stock and Warrants

On January 22, 2024, the Company closed an offering under a Securities Purchase Agreement with purchasers named therein pursuant to which the Company sold approximately 465 shares of common stock, approximately 5,968 pre-funded warrants ("PFWs"), and approximately 12,864 warrants to purchase common stock (the "January 2024 Warrants"), in a registered direct offering at a purchase price of $1,127.28 per share (or $1,118.04 per PFW) (the "January 2024 RDO"). The January 2024 Warrants became exercisable commencing on issuance and are exercisable for three and one-half years from the date of issuance at an exercise price of $1,127.28 per share. Net proceeds from the January 2024 RDO, after deducting fees payable to the placement agent and other offering expenses, were approximately $6.1 million. The PFWs sold in the January 2024 RDO were exercisable at an exercise price of $9.24 per share. All PFWs sold in the January 2024 RDO were exercised prior to April 30, 2024. In connection with the January 2024 RDO, the Company also issued the placement agent warrants to purchase up to approximately 386 shares of common stock (the "January 2024 Placement Agent Warrants"). The January 2024 Placement Agent Warrants became exercisable on issuance, expire three and one-half years following the date of sale and have an exercise price per share of $1,409.10. See Note 13.

On July 22, 2024, the Company entered into a Placement Agency Agreement with ThinkEquity LLC pursuant to which the Company issued and sold approximately 10,823 shares of common stock in a best efforts public offering at a purchase price of $277.20 per share (the "July 2024 Offering"). Net proceeds from the July 2024 Offering, after deducting discounts, commissions and fees paid to the placement agent and other offering expenses, were approximately $2.4 million. In connection with the July 2024 Offering, the Company also issued warrants to the placement agent to purchase up to approximately 542 shares of common stock (the "July Placement Agent Warrants"). The July Placement Agent Warrants become exercisable January 18, 2025, expire July 22, 2029, and have an exercise price of $346.50 per share. See Note 13.

On December 2, 2024, the Company closed an offering under a Securities Purchase Agreement with purchasers named therein pursuant to which the Company sold 6,180 shares of common stock, 16,786 PFWs, together with 22,966 Series C Warrants to purchase common stock (the "Series C Warrants"), and 22,966 Series D Warrants to purchase common stock (the "Series D Warrants") in a private offering at a purchase price of $348.35 per share (or $348.25 per PFW) (the "2024 PIPE"). The Series C and Series D Warrants became exercisable commencing on shareholder approval which occurred February 25, 2025. The Series C Warrants are exercisable for five years from shareholder approval; the Series D Warrants are exercisable for two and one-half years from such approval. The initial exercise prices for the Series C and Series D Warrants was $348.35 per share, subject to adjustments and resets. In addition, the Series D Warrants included an alternative cashless exchange provision whereby the holder could exchange each Series D Warrant for three shares of Common Stock. Net proceeds from the 2024 PIPE, after deducting fees payable to the placement agent and other offering expenses, were approximately $7.2 million. The PFWs sold in the 2024 PIPE were exercisable at an exercise price of $0.0924 per share. All PFWs sold in the 2024 PIPE were exercised prior to March 31, 2025. See Note 13. The Company accounts for the Series C and D Warrants in accordance with the guidance contained in ASC 815-40. Such guidance provides that because the Series C and D Warrants do not meet the criteria for equity treatment thereunder, they must be recorded as a liability.

On March 23, 2025, the Company entered into a Placement Agency Agreement with ThinkEquity LLC pursuant to which the Company issued and sold 366,072 shares of common stock and warrants (the "March 2025 Offering Warrants") to purchase 366,072 shares of common stock at an exercise price of $24.08 per share in a best efforts public offering at a purchase price of $27.44 per share and accompanying warrant (the "March 2025 Offering"). Net proceeds from the March 2025 Offering, after deducting discounts, commissions and fees paid to the placement agent and other offering expenses, were approximately $8.9 million. In connection with the March 2025 Offering, the Company also issued warrants to the placement agent to purchase up to 18,304 shares of common stock

(12) Stockholders' Equity (Deficit) (continued)

(the "March 2025 Placement Agent Warrants"). The March 2025 Placement Agent Warrants became exercisable on issuance, expire March 24, 2030, and have an exercise price of $29.96 per share. See Note 13.

(i) Registration Rights Agreement

In connection with the Acquisition, the Company entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the holders (the "Holders") of the Common Stock, the Series A Preferred Stock and the Series B Preferred Stock issued in connection with the Acquisition (collectively the "Acquisition Transaction Shares"). Pursuant to the Registration Rights Agreement, the Company was required to prepare and file a resale registration statement with the SEC on or prior to the 75th calendar day following the Closing (the "Filing Deadline"), with respect to the shares of Common Stock issued in the Acquisition and the shares of Common Stock issuable upon conversion of the Series A Preferred Stock and the Series B Preferred Stock issued in the Acquisition, subject to the Beneficial Ownership Limitation. The Company and the Holders agreed to extend the Filing Deadline to a date to be determined.

(13) Warrants

Except as noted otherwise, all the warrants described below were outstanding as of December 31, 2025, and are accounted for as a component of stockholders' equity. All PFWs issued in the Company's financings described herein were exercised on or before January 10, 2025.

In connection with the IPO, the Company granted the underwriter warrants (the "IPO Underwriter Warrants") to purchase up to approximately 20 shares of Company common stock at an exercise price of $3,696,000.00 per share. The IPO Underwriter Warrants have a five-year term and were not exercisable prior to January 9, 2022.

In connection with the February RDO, the Company issued the February Placement Agent Warrants to purchase up to approximately four shares of common stock. The February Placement Agent Warrants became exercisable commencing August 17, 2023, expire February 16, 2028, and have an exercise price per share of $486,948.00 per share.

In connection with an agreement the Company entered into with a consultant in February 2023, the Company agreed to issue warrants (the "Consultant Warrants") to purchase up to approximately one share of common stock at $369,600.00 per share. The Consultant Warrants became exercisable any time after August 23, 2023, until February 23, 2028.

In connection with the June RDO, the Company issued approximately 55 Series A-1 Warrants and approximately 55 Series A-2 Warrants, which became exercisable commencing June 9, 2023. The Series A-1 and Series A-2 Warrants expire three years following the date of sale and have an exercise price of $348.35 per share. The Company also issued warrants to the June RDO placement agent to purchase up to approximately 107 shares of common stock. The June RDO Placement Agent Warrants became exercisable commencing June 9, 2023, expire three years after issuance, and have an exercise price per share of $161,700.00 per share.

In connection with the September Offering, the Company issued warrants to the underwriter to purchase up to approximately 23 shares of common stock. Approximately 16 additional warrants were issued to the underwriter in October 2023 in connection with the underwriter's partial exercise of the overallotment option. The September Offering Underwriter Warrants became exercisable commencing 180 days after issuance, expire five years following the date of sale and have an exercise price per share of $23,562.00.

In connection with the December RDO, the Company issued the December Placement Agent Warrants to purchase up to approximately nine shares of common stock. The December Placement Agent Warrants became exercisable on issuance, expire five years following the date of issuance, and have an exercise price per share of $11,180.40.

In connection with the January 2024 RDO, the Company issued the January 2024 Warrants to purchase up to approximately 12,864 Warrants to purchase common stock at a purchase price of $1,127.28 per share. The January 2024 Warrants became exercisable commencing on issuance and are exercisable for three and one-half years from the date of issuance generally at an exercise price of $1,127.28 per share. All PFWs sold in the January 2024 RDO were exercised prior to April 30, 2024. In connection with the January

(13) Warrants (continued)

2024 RDO, the Company also issued the placement agent the January 2024 Placement Agent Warrants to purchase up to approximately 386 shares of common stock. The January 2024 Placement Agent Warrants became exercisable on issuance, expire three and one-half years following the date of sale and have an exercise price per share of $1,409.10.

In connection with the July 2024 Offering, the Company issued to the placement agent the July Placement Agent Warrants to purchase up to approximately 542 shares of common stock. The July Placement Agent Warrants became exercisable January 18, 2025, expire July 22, 2029, and have an exercise price of $346.50 per share.

In connection with the 2024 PIPE, the Company issued approximately 22,966 Series C Warrants and 22,966 Series D Warrants. The Series C and Series D Warrants became exercisable commencing on shareholder approval which occurred February 25, 2025. The Series C Warrants are exercisable for five years from shareholder approval; the Series D Warrants were exercisable for two and one-half years from such approval. The initial exercise price for the Series C and Series D Warrants was $348.35 per share, subject to adjustments and resets. In addition, the Series D Warrants included an alternative cashless exchange provision whereby the holder could exchange each Series D Warrant for three shares of Common Stock. The Series C Warrants and the Series D Warrants are accounted for as liabilities. All Series D warrants were exchanged for common stock in the first quarter 2025.

In connection with the March 2025 Offering, the Company issued the March 2025 Offering Warrants to purchase up to 366,072 shares of common stock at an exercise price of $24.08 per share. The March 2025 Offering Warrants became exercisable commencing on issuance and are exercisable for five years from the date of issuance. In connection with the March 2025 Offering, the Company also issued the placement agent the March 2025 Placement Agent Warrants to purchase up to 18,304 shares of common stock. The March 2025 Placement Agent Warrants became exercisable on issuance, expire five years following the date of sale and have an exercise price of $29.96 per share.

The following table summarizes the Company's outstanding warrants at December 31, 2025:

Description	Number of Shares	Exercise Price Per Share
IPO Underwriter Warrants	20	$ 3,696,000
February 2023 Placement Agent Warrants	4	486,948
February 2023 Consultant Warrants	1	369,600
June 2023 Series A-1 warrants	55	348.35
June 2023 Series A-2 warrants	55	348.35
June 2023 Placement Agent Warrants	7	161,700.00
September 2023 Underwriter Warrants	33	23,562.00
October 2023 Underwriter Overallotment Warrants	16	23,562.00
December 2023 Placement Agent Warrants	18	11,180.40
January 2024 Warrants	6,749	1,127.28
January 2024 Warrants	5,423	438.90
January 2024 Placement Agent Warrants	388	1,409.10
July 2024 Placement Agent Warrants	548	346.50
December 2024 Series C Warrants	144,682	69.67
March 2025 Offering Warrants	366,080	24.08
March 2025 Placement Agent Warrants	18,290	29.96

Approximately 697 of the January 2024 Warrants were exercised in the first half of 2024. In December 2024, the Company modified the exercise price applicable to the Series A-1 and Series A-2 Warrants to $348.35, and certain January 2024 Warrants to $438.90 per share. In connection with the modification, the Company recorded a deemed dividend in the aggregate of $30,601. During the first quarter 2025, all Series D warrants were exchanged for common stock representing 425,895 shares after reset adjustments.

(14) Share-Based Compensation

In April 2020, the Board approved the TransCode Therapeutics, Inc. 2020 Stock Option and Incentive Plan (the "2020 Plan") providing for the issuance of options or other awards to purchase up to approximately five shares of the Company's common stock. Following the closing of the IPO, the Board determined not to make any further awards under the 2020 Plan. In March 2021, the Company's 2021 Stock Option and Incentive Plan (the "2021 Plan") was approved by the Company's Board and stockholders and became effective upon the effectiveness of the IPO. The 2021 Plan initially provided for the issuance of options or other awards to purchase up to approximately seven shares of the Company's common stock. The number of options or other awards available under the 2021 Plan increased approximately one share in January 2022, approximately one share in January 2023, approximately 34 shares in January 2024, approximately 3,247 shares in June 2024, and approximately 1,838 shares in January 2025.

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

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

Of options outstanding at December 31, 2025, approximately 10 were awarded under the 2020 Plan and approximately 2,025 were awarded under the 2021 Plan.

At December 31, 2025, there were approximately 10 options outstanding under the 2020 Plan that were vested and exercisable and approximately 2,025 options outstanding under the 2021 Plan that were vested and exercisable. Information about options to purchase common stock of the Company under both Plans is as follows:

	Number of shares	Weighted average exercise price per share	Weighted average contractual term (years)
Outstanding at December 31, 2023	85	$ 387,691.92	3.7
Granted	2,100	1,108.80	9.2
Exercised	—	—	—
Forfeited	(83)	13,365.75	—
Outstanding at December 31, 2024	2,102	2,206.40	9.4
Granted	—	—	—
Exercised	—	—	—
Forfeited	(67)	106,636.80	—
Outstanding at December 31, 2025	2,035	$ 16,958.12	8.4

The intrinsic value of the outstanding options as of December 31, 2025, was $0.

(14) Share-Based Compensation (continued)

Option Valuation

No options were granted in the year ended December 31, 2025. The assumptions that the Company used to determine the grant-date fair value of options granted in the year ended December 31, 2024, were as follows:

	Year Ended December 31, 2024
Risk-free interest rate	4.44%
Expected term (in years)	6.0
Expected volatility	128.8%
Expected dividend yield	—
Fair value per share of underlying stock	$29.68 - $30.24

The weighted average grant date fair value per share of the options granted in the year ended December 31, 2024, was $997.64.

The Company recorded share-based compensation expense of $485,428 and $1,699,999 during the years ended December 31, 2025 and 2024, respectively, all of which related to stock options. Because all outstanding options have vested at December 31, 2025, the remaining share-based compensation expense to be recognized in the future is $0.

(15) Employee Stock Purchase Plan

In 2021, the Company adopted an Employee Stock Purchase Plan (the "ESPP") to provide eligible employees of the Company with opportunities to purchase shares of the Company's common stock. The ESPP initially provided for the purchase of an aggregate of up to approximately six shares of common stock. The number of shares of common stock available through the ESPP increased by approximately three shares in each of January 2022 through January 2025, and may be increased each subsequent year by up to approximately three shares.

(16) Net Loss per Share

The Company reported net losses for the years ended December 31, 2025 and 2024. Reported basic and diluted net loss per share attributable to common stockholders are the same for each period because shares issuable in connection with Contingent Securities have been excluded from the computation of diluted weighted-average shares outstanding. The effect of their inclusion would have been antidilutive. In accordance with ASC 260-10-45-13, a pre-funded, or penny, warrant is an instrument that requires the holder to pay little or no consideration to receive the shares upon exercise of the warrant. Since the shares underlying the PFWs are issuable for little or no consideration, the Company considered them outstanding in the context of basic earnings per share.

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

	Years ended December 31,	
	2025	2024
Basic and diluted net loss per share		
Net loss attributable to common stockholders	$ (36,271,287)	$ (16,785,572)
Weighted-average common shares outstanding	689,713	12,558
Net loss per share	$ (52.59)	$ (1,336.63)

(17) Income Taxes

The Company's federal and state provision (benefit) for income taxes was $226,068 and $0 for the years ended December 31, 2025 and 2024, respectively. The federal deferred provision (benefit) for income taxes was $92,487 and $0 for the years ended December 31, 2025 and 2024, respectively. The state deferred provision (benefit) for income taxes was $133,601 and $0 for the years ended December 31, 2025 and 2024, respectively.

A reconciliation of income tax provision (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the consolidated financial statements is as follows:

	Years Ended December 31,			
	2025		2024	
Federal income tax benefit at statutory rate	$ (7,278,826)	21.00 %	$ (3,562,919)	21.00 %
State and local income tax, net of federal (national) income tax effect*	133,601	(0.39)%	—	— %
Foreign tax effects				
Effect of changes in tax laws or rates enacted in the current period	—	— %	—	— %
Permanent differences	—	— %	—	— %
Tax credits	—	— %	—	— %
Change in valuation allowance	5,155,083	(14.87)%	2,574,447	(15.70)%
Nontaxable or nondeductible items				
Share-based compensation	102,022	(0.29)%	199,069	(1.17)%
Change in fair value of derivatives and warrants	1,948,237	(5.62)%	366,862	(2.16)%
Other	165,952	(0.48)%	422,541	(2.49)%
Changes in unrecognized tax benefits				
Actual income tax expense and effective tax rate	$ 226,069	(0.65)%	$ —	(0.52)%

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for consolidated financial statement and income tax purposes. The significant components of the Company's deferred tax assets consist of the following:

	December 31,	
	2025	2024
Net operating loss carryforwards	$ 13,484,723	$ 8,893,509
Capitalized research and development	8,610,208	6,139,921
Capitalized patent and other costs	735,869	20,680
Stock-based compensation	191,232	303,419
Accrued expenses	57,130	40,210
Fixed assets	16,837	6,461
Research and development tax credit carryforwards	531,134	729,985
Subtotal deferred tax assets before valuation allowance	23,627,133	16,134,185
Less valuation allowance	(22,818,973)	(16,134,185)
Deferred tax assets	808,160	—
Deferred tax liability		
Fixed assets	(1,034,228)	—
Net deferred taxes	$ (226,068)	$ —

The Company had U.S. federal net operating loss ("NOL") carryforwards of $49,502,165 and $30,570,980 for the years ended December 31, 2025 and 2024 respectively, which may be available to offset future taxable income. Federal NOL carryforwards

(17) Income Taxes (continued)

generated in 2017 and prior of $38,297 will expire beginning in 2036. The remaining federal NOL carryforwards generated in 2018 and later do not expire. However, they are subject to the 80% limitation when utilized. The Company also had U.S. state NOL carryforwards of $48,880,839 and $29,949,653 for the years ended December 31, 2025 and 2024, respectively, which may be available to offset future taxable income and will expire beginning in 2036.

The Company had U.S. federal research and development tax credit carryforwards of $549,780 and $549,780 for the years ended December 31, 2025 and 2024, respectively, available to reduce future income tax liabilities. These will expire beginning in 2042. The Company also had U.S. state research and development tax credit carryforwards of $189,418 and $495,079 for the years ended December 31, 2025 and 2024, respectively, available to reduce future income tax liabilities. Of the U.S. state research and development tax credit carryforwards, $7,013 have an indefinite carryforward and the remainder expire beginning in 2036.

The Company has recorded a full valuation allowance against its net deferred tax assets, except the “naked credit” deferred tax liability, as of December 31, 2025 and 2024, because the Company has determined that it is more likely than not that these assets will not be fully realized due to the significant uncertainty about the realization of the deferred tax asset until the Company can operate profitably. The Company experienced a net change in valuation allowance of $6,776,067 and $3,471,485 in the years ended December 31, 2025 and 2024, respectively. Notwithstanding the full valuation allowance, the Company carries a net deferred tax liability of $226,068 reflecting a “naked credit” arising from an indefinite-lived intangible deferred tax liability that cannot be scheduled to reverse concurrently with the Company’s deferred tax assets, as the associated NOL utilization is subject to the 80% taxable income limitation under IRC §172, leaving a portion of the indefinite-lived intangible DTL without an offsetting DTA.

Under the provisions of the Internal Revenue Code, the NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed financings since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future. The Company has not analyzed the historical or potential impact of its financings on beneficial ownership, and therefore, no determination has been made whether the net operating loss carryforward is subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there could be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company’s tax years from 2020 to the present remain open for review. All open years may be examined to the extent that tax credits or NOL carryforwards are used in future periods. The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2025 and 2024, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company’s statements of operations.

A reconciliation of the Company’s unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Balance at beginning of year	$ 228	$ 353
Increase for tax positions of prior years	(54)	(125)
Increase based on tax positions related to current year	—	—
Balance at end of year	$ 174	$ 228

(17) Income Taxes (continued)

Due to the Company's valuation allowance, the $0.2 million of unrecognized tax benefits would not affect the effective tax rate, if recognized. It is the Company's practice to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2025, the Company had no accrued interest and penalties related to uncertain tax positions. The Company does not expect any material changes to the estimated amount of liability associated with the Company's uncertain tax positions within the next 12 months.

The Protecting Americans from Tax Hikes Act of 2015 ("PATH Act") made permanent the federal credit for increasing research activities ("R&D credit"). The PATH Act also included a provision that allowed a qualified small business to utilize a portion of its annual R&D credit as a payroll tax offset for up to $250,000 of its FICA payroll tax. The Company qualifies for this provision and has recorded payroll tax prepayments of $250,000 and $172,492 for 2022 and 2021, respectively. These benefits were able to be used beginning in the first quarter of 2023 and do not expire. The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was signed into law in 2020 and contained several new or changed income tax provisions. The Company has evaluated the tax provisions of the CARES Act and determined the impact to be either immaterial or not applicable. The Inflation Reduction Act of 2022 modified the PATH Act by adding an additional payroll tax offset of up to $250,000 against the Medicare payroll tax beginning in 2023. The Company is evaluating the benefits available under this provision.

Pursuant to the Tax Cuts and Jobs Act, as modified by the One Big Beautiful Bill Act of 2025, domestic R&D expenditures incurred after December 31, 2024 are no longer required to be capitalized and may be deducted in the current year. For 2025, the Company capitalized approximately $5.7 million of foreign R&D expenditures, which continue to be amortized over 15 years using the mid-year convention, and recognized amortization on all prior-year domestic and foreign Section 174 capitalizations. The Company has established a net deferred tax asset of approximately $6.8 million related to this item, fully offset by a valuation allowance. Additionally, pursuant to IRC §59(e), the Company elected to capitalize and amortize its 2025 domestic research and experimental expenditures over 10 years; the resulting deferred tax asset of approximately $1.8 million is separate from the capitalized research and development balance above and is fully offset by the valuation allowance.

(18) Segment Reporting

ASC 280, "Segment Reporting," establishes standards for reporting information about operating segments on a basis consistent with the Company's internal organization structure as well as information about services categories, business segments and major customers in consolidated financial statements. The Company has a single reportable business unit segment, development of drug candidates designed to treat cancer, and one reportable country segment, the United States of America, for the years ended December 31, 2025 and 2024.

The provisions of ASC 280 establish standards for the way public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in consolidated financial statements issued to shareholders. In accordance with ASC 280, the Company's chief operating decision maker has been identified as its Chief Executive Officer and Chief Financial Officer (together, the "CODM"). The Company's CODM reviews the consolidated financial information presented for purposes of allocating resources and evaluating its consolidated financial performance for the entire Company. Accordingly, the Company has determined that it operates in a single reportable segment. All of the Company's long-lived assets are located in the United States. Since the Company operates in one operating segment, all required financial segment information can be found in the consolidated financial statements.

The Company does not distinguish between markets or segments for the purpose of internal reporting. The majority of the Company's long-lived tangible assets are located in Michigan, US, and its deferred tax assets are US-related.

Existing guidance, which is based on a management approach to segment reporting, establishes requirements to report selected segment information quarterly and to report annually entity-wide disclosures about products and services, major customers, and the countries in which the entity holds material assets and reports revenue. All material operating units qualify for aggregation under "Segment Reporting" due to their similar activities and similarities in economic characteristics; and similarities in procurement, manufacturing and distribution processes.

(19) Subsequent Events

For its consolidated financial statements as of December 31, 2025, the Company evaluated subsequent events through April 15, 2026, the date on which these consolidated financial statements were issued.

Unleash License

On March 2, 2026, the Company entered into an agreement with Unleash Immuno Oncolytics, Inc. ("Unleash"). The Unleash Licensing Agreement provided the Company with a license and other rights to technologies owned or licensed by Unleash. In consideration for the transaction, the Company issued 1,136,364 shares of its Series C Non-Voting Convertible Preferred Stock to Unleash.

Yorkville Financing

On April 7, 2026, the Company entered into a Standby Equity Purchase Agreement (the "SEPA") with YA II PN, LTD, a Cayman Islands exempt limited partnership, ("Yorkville") pursuant to which the Company has the right to sell to Yorkville up to $14 million of shares of Common Stock, subject to certain limitations and conditions set forth in the SEPA, from time to time during the term of the SEPA (the "Commitment Amount"). Sales of shares of Common Stock to Yorkville under the SEPA, and the timing of any such sales, are at the Company's option, and the Company is under no obligation to sell any shares of Common Stock to Yorkville under the SEPA. Upon the satisfaction of the conditions to Yorkville's purchase obligation set forth in the SEPA, the Company can, at its sole discretion, direct Yorkville to purchase specified amounts of Common Stock. The purchase price per share for each advance is set at 97% of the lowest daily volume weighted average price ("VWAP") during the three consecutive trading days beginning on the date upon which the Advance Notice (as defined in the SEPA) is delivered. Actual sales of Common Stock to Yorkville under the SEPA will depend on a variety of factors to be determined by the Company, in its sole discretion, from time to time, which may include, among other things, market conditions, the trading price of the Company's Common Stock and determinations by the Company as to appropriate sources of funding for its business and operations.

In connection with the SEPA, and subject to the conditions set forth therein, Yorkville has also agreed to advance to the Company up to $6.0 million, less certain amounts as described below, to be paid in two tranches (each, a "Pre-Paid Advance" and, together, the "Pre-Paid Advances"), in exchange for the Company's issuance to Yorkville of convertible promissory notes (each, a "Convertible Note" and, together, the "Convertible Notes"). Pursuant to the Convertible Notes and the SEPA, Yorkville may convert all or any portion of the outstanding principal amount, accrued but unpaid interest, and other amounts outstanding under the Convertible Notes into shares of Common Stock, at any time and from time to time during the term of the Convertible Notes.

The first Pre-Paid Advance is expected to be disbursed to the Company the day after it files this Annual Report on Form 10-K. In exchange for the first Pre-Paid Advance, the Company will issue to Yorkville a Convertible Note in the principal amount of $1.0 million (the "First Convertible Note"), with a purchase price discount of 5.0% (or $50,000). The First Convertible Note will be convertible into Common Stock at the lower of (i) a fixed conversion price equal to 115% of the VWAP on the day prior to the issuance of the Note and (ii) 95% of the lowest daily VWAP during the seven consecutive trading days immediately preceding the conversion date, but in no event lower than 20% of last reported trading price of the Company's Common Stock on Nasdaq as quoted by Bloomberg (the "First Convertible Note Conversion Price") as of the trading day immediately prior to the date of the SEPA (the "Floor Price"). After accounting for the purchase price discount, the Company expects to receive gross proceeds of $950,000 for the First Convertible Note.

The second tranche of the Pre-Paid Advance is expected to be disbursed to the Company in exchange for the issuance to Yorkville of a Convertible Note in the principal amount of $5.0 million (the "Second Convertible Note"). The Second Convertible Note is expected to be issued with a purchase price discount of 5.0% (or $250,000) and will be convertible into Common Stock at the lower of (i) a price equal to 115% of the VWAP on the day prior to issuance of the Second Convertible Note and (ii) 95% of the lowest daily VWAP during the seven consecutive trading days immediately preceding the conversion date, but in no event lower than the Floor

(19) Subsequent Events (continued)

Price (the "Second Convertible Note Conversion Price," and together with the First Convertible Note Conversion Price, the "Conversion Price"). The Second Convertible Note will be issued on the second trading day after the later of (i) the registration statement filed pursuant to the SEPA, including any prospectus, amendments and supplements thereto, (the "Yorkville Registration Statement") first becoming effective under the Securities Act, (ii) the Company's receipt of stockholder approval to issue shares of Common Stock to Yorkville under the SEPA in excess of the Exchange Cap (defined below) and (iii) the approval by Nasdaq of the initial listing application required under Nasdaq Listing Rules 5110 and 5635(b). After accounting for the purchase price discount, the Company expects to receive gross proceeds of $4,750,000 pursuant to the Second Convertible Note.

Interest on the outstanding balances of the Convertible Notes will accrue at an annual rate of 5.0%, subject to an increase to 18% upon an event of default (as defined in the Convertible Notes). The maturity date of each Convertible Note will be 18 months from the date on which it is issued. The applicable maturity date of each Convertible Note may be extended by the Company, at its option, for six months on two occasions by providing written notice to Yorkville. On the applicable maturity date, any portion of the outstanding principal amount and accrued but unpaid interest that remains outstanding on such Convertible Note will automatically be converted at the then applicable Conversion Price, provided that if any Equity Condition (as defined in the Form of Promissory Note) is not satisfied, the applicable maturity date will be automatically extended until all Equity Conditions have been satisfied.

The sale and issuance of shares under the SEPA, including upon conversion of the Convertible Notes at Yorkville's option and the sale of shares of Common Stock to Yorkville at the Company's option, is subject to an exchange cap limiting the total number of shares issuable to Yorkville to 183,301 (19.99% of outstanding shares of Common Stock before the effective date of the SEPA) (the "Exchange Cap"), unless the Company obtains stockholder approval to issue shares to Yorkville exceeding the Exchange Cap (the "Yorkville Issuance Approval"). Additionally, Yorkville may not own more than 9.99% of the Company's outstanding Common Stock at any time unless it provides written notice of its intention to increase this limit, effective after 65 days.

Sponsored Research Agreement

On April 11, 2026, the Company entered into a Sponsored Research Agreement (the "SRA") with Michigan State University ("MSU") pursuant to which MSU will conduct certain research projects in collaboration with the Company. There are no upfront financial obligations on the Company under the SRA. The Company will pay MSU agreed upon costs for conduct of the research. Each project under the SRA will have its own budget and payment schedule, with payments generally due monthly upon receipt of invoices from MSU.

EXECUTIVE OFFICERS

Philippe P. Calais, Pharm D, Ph.D.
Chief Executive Officer

Thomas A. Fitzgerald, MBA Chief
Financial Officer and Vice President

BOARD OF DIRECTORS

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CORPORATE INFORMATION

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Form 10-K

The Company's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on April 15, 2026, except for exhibits, is printed as part of this 2025 Annual Report. Additional copies are available without charge upon written request.

Please address all requests to:
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